UNITED STATES DISTRICT COURT
DISTRICT OF MONTANA
GREAT FALLS DIVISION

CITY OF GREAT FALLS; COUNTY OF ANACONDA-DEER LODGE; COUNTY OF LAKE; and **CITY OF MISSOULA**, *Plaintiffs*, vs. **PURDUE PHARMA L.P.**; **PURDUE PHARMA INC.**; **THE PURDUE FREDERICK COMPANY**; **CEPHALON, INC.**; **JOHNSON & JOHNSON**; **JANSSEN PHARMACEUTICALS, INC.**; **ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.** n/k/a JANSSEN PHARMACEUTICALS, INC.; **JANSSEN PHARMACEUTICA INC.** n/k/a JANSSEN PHARMACEUTICALS, INC.; **ENDO HEALTH SOLUTIONS INC.**; **ENDO PHARMACEUTICALS, INC.**; **ALLERGAN PLC** f/k/a ACTAVIS PLC; **ALLERGAN FINANCE, LLC** f/k/a ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC.; **WATSON LABORATORIES, INC.**; **ACTAVIS LLC**; **ACTAVIS PHARMA, INC.** f/k/a WATSON PHARMA, INC.;	**Civil Action No.** **COMPLAINT AND JURY DEMAND**

AMERISOURCEBERGEN CORPORATION;
AMERISOURCEBERGEN DRUG CORPORATION;
CARDINAL HEALTH, INC.;
CARDINAL HEALTH 110, LLC;
MCKESSON CORPORATION;
CVS HEALTH CORPORATION;
CVS INDIANA, L.L.C.;
CVS PHARMACY, INC.; and
DOES 1 – 100, INCLUSIVE,

Defendants.

PLAINTIFFS' ORIGINAL COMPLAINT

TO THE HONORABLE JUDGE OF SAID COURT:

NOW COME Plaintiffs, City of Great Falls, Montana, County of Anaconda-Deer Lodge, Montana, County of Lake, Montana, and City of Missoula, Montana, by and through the undersigned attorneys (hereinafter "Cities" or "Counties" or "Plaintiffs"), against Defendants Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Cephalon, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., Allergan PLC f/k/a Actavis PLC, Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., AmerisourceBergen Corporation,

AmerisourceBergen Drug Corporation, Cardinal Health, Inc., Cardinal Health 110, LLC, McKesson Corporation, CVS Health Corporation, CVS Indiana, L.L.C., CVS Pharmacy, Inc., and Does 1 – 100, alleges as follows:

I. INTRODUCTION

1. The United States is in the midst of an opioid epidemic caused by Defendants' fraudulent marketing, sales, and distribution of prescription opioids ("opioids") that has resulted in addiction, criminal activity, and loss of life.[1] Americans "consume 85% of all the opioids in the world" and are "the most medicated country in the world…."[2] The opioid crisis has been described as "the AIDS epidemic of our generation, but even worse."[3] On October 26, 2017, President Donald Trump "declared a nationwide public health emergency to combat the opioid crisis."[4]

2. In 1997, each person in the United States, on average, consumed 96 mg morphine equivalents. In 2010 that number increased to 710 mg per person.[5] This amount has been estimated as the equivalent to 7.1 kg of opioids per 10,000 people

[1] L. Manchikanti, *Opioid Epidemic in the United States*, Pain Physician, Jul. 2012, at 1, www.painphysicianjournal.org, attached hereto as Exhibit A.
[2] David Wright, *Christie on Opioids: "This is the AIDS Epidemic of Our Generation, but even Worse,"* CNN, Oct. 27, 2017, *available at* http://www.cnn.com/2017/10/27/politics/chris-christie-opioid-commission-aids-cnntv/index.html; Manchikanti, Ex. A, at 16 ("Gram for gram, people in the United States consume more narcotic medication than any other nation worldwide.").
[3] Wright, *supra*.
[4] Dan Merica, *What Trump's Opioid Announcement Means – and Doesn't Mean*, CNN, Oct. 26, 2017, *available at* http://www.cnn.com/2017/10/26/politics/national-health-emergency-national-disaster/index.html.
[5] Manchikanti, Ex. A, at 14.

– or enough to supply each American with 5 mg of hydrocodone every 6 hours for 45 days.[6]

3. It's no surprise that in 2016 alone, health care providers wrote more than 289 million prescriptions for opioids, enough for *every adult in the United States* to have more than one bottle of pills.[7]

4. Unfortunately, using opioids too often leads to addiction and overdose from opioids. It was estimated as early as 2001 that up to 40% of chronic pain patients were addicted to opioid pain medication.[8] Almost 2 million Americans were addicted to opioids in 2014.[9] To put the opioid crisis in perspective, the statistics demonstrate:

- Roughly 21 to 29 percent of patients prescribed opioids for chronic pain misuse them;
- Between 8 and 12 percent develop an opioid use disorder; and
- About 80 percent of people who use heroin first misused prescription opioids.[10]

5. From 1999 to 2017, more than 700,000 people have died from a drug overdose; around 68% of the more than 70,200 drug overdoses in 2017 involved an opioid.[11] In 2017, the number of overdose deaths involving opioids was 6 times

[6] *Id.*
[7] *Prevalence of Opioid Misuse*, BupPractice, Sept. 7, 2017, *available at* https://www.buppractice.com/node/15576.
[8] *Prescription Drugs: Abuse and Addiction*, National Institute of Drug Abuse (NIH Publication), Jul. 2001, at 13.
[9] *National Survey on Drug Use and Health*, Substance Abuse and Mental Health Services Administration, 2014.
[10] *Opioid Overdose Crisis*, National Institute on Drug Abuse, Jan. 2018, *available at* https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis.
[11] https://www.cdc.gov/drugoverdose/epidemic/index.html

higher than in 1999.[12] Currently, on average, 130 Americans die every day from an opioid overdose.[13]

6. The Opioid Epidemic proximately caused by the Defendants is so pervasive that the lifetime risk of dying from an accidental overdose of opioids exceeds the risk of dying from motor vehicle accidents, drowning, or fire.[14]

7. In fact, accidental drug overdose deaths, of which reportedly at least two-thirds are opioid overdoses, are the leading cause of death for Americans under the age of 50. And these accidental opioid drug overdose deaths exceed the number of deaths caused by cars or guns. A report from the CDC found that from July 2016 to September 2017, emergency visits due to suspected opioid overdoses continued to climb approximately 30% across the nation.[15] The increase was seen in adults of all age groups and in men and women in all geographic areas.[16]

8. The Cities and Counties are responsible for programs and services that require Plaintiffs to expend resources generated through state and federal aid, property taxes, fees and other permissible revenue sources; and provide programs and services such as the City-County Health Department and Court Services, which

[12] *Id.*
[13] *Id.*
[14] Flower, K., Senthilingam, M. (2019, Jan. 14). *Odds of Dying from Accidental Opioid Overdose in the US Surpass Those of Dying in a Car Accident.* CNN. https://www.cnn.com/2019/01/14/health/opioid-deaths-united-states-surpass-road-accidents/index.html
[15] Jacqueline Howard, *ER Visits for Opioid Overdose up 30%, CDC Study Finds*, CNN, Mar. 6, 2018.
[16] *Id.*

become more burdened every year due to the costs associated with providing the programs and services to deal with the opioid abuse.

9. Plaintiffs' ability to generate revenue through property taxes is limited by state law. However, the Cities' and Counties' expenditures addressing, combating, and otherwise trying to deal with opioid abuse are monies that cannot be used for other important programs and services that the Cities and Counties provide to its citizens, residents and visitors.

10. Over the next decade, the average number of deaths due to opioids is expected to be 500,000.[17] Proof that the opioid epidemic is far from slowing is the latest statistic that approximately 72,000 Americans died from drug overdoses last year in 2017.[18] This increase is due to a growing number of Americans using opioids and the opioids themselves are becoming more deadly.[19] The economic burden caused by opioid abuse in the United States is at least $78.5 billion,[20] including lost productivity and increased social services, health insurance costs, increased criminal

[17] Max Blau, *STAT forecast: Opioids Could Kill Nearly 500,000 American in the next Decade*, STAT, June 27, 2017, *available at* https://www.statnews.com/2017/06/27/opioid-deaths-forecast/; *see also* Wes Rapaport, *Advocates for Painkiller Advocates Wants Society to Meet Them Halfway*, Big Country, Feb. 18, 2018 (stating the number of opioid overdose deaths is going to go up for at least several more years and explaining how Operation Naloxone has administered more than $1 million of the powerful antidote).
[18] Margot Sanger-Katz, *Bleak New Estimates in Drug Epidemic: A Record 72,000 Overdose Deaths in 2017*, The New York Times, Aug. 15, 2018, https://www.nytimes.com/2018/08/15/upshot/opioids-overdose-deaths-rising-fentanyl.html (representing a 9.5 percent increase from 2016).
[19] *Id.*
[20] *CDC Foundation's New Business Pulse Focuses on Opioid Overdose Epidemic*, Centers for Disease Control and Prevention, Mar. 15, 2017, *available at* https://www.cdc.gov/media/releases/2017/a0315-business-pulse-opioids.html.

justice presence and strain on judicial resources, and substance abuse treatment and rehabilitation.[21]

11. This epidemic did not occur by chance. Defendants manufacture, market, distribute, and sell prescription opioids, including but not limited to, brand-name drugs like OxyContin, Opana, Percocet, Percodan, Duragesic, Ultram, Ultracet, and generics like oxycodone, oxymorphone, hydromorphone, hydrocodone, fentanyl, and tramadol, which are powerful narcotics.

12. Historically, opioids were considered too addictive and debilitating for treating non-cancer chronic pain,[22] such as back pain, migraines, and arthritis, and were used only to treat short-term acute pain or for palliative or end-of-life care.

13. By the late 1990s or early 2000s, however, each Manufacturing Defendant began a marketing scheme to persuade doctors and patients that opioids were not addictive and should be used ubiquitously and perpetually to treat moderate, non-cancer chronic pain.[23] Defendants' efforts to "increase opioid use" and their campaign emphasizing "the alleged undertreatment of pain continue to be significant factors of the [opioid] escalation."[24] Defendants reassured the medical community that opioids were not addictive and doctors prescribed them at a higher

[21] *Opioid Overdose Crisis*, *supra*.
[22] "Chronic pain" means non-cancer pain lasting three months or longer.
[23] *See e.g.*, *Opioid Overdose Crisis*, National Institute on Drug Abuse, Jan. 2018, *available at* https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis (explaining the greater rate of prescribing opioids due to misinformation to physicians, which led to a diversion and misuse of opioids before anyone knew opioids were highly addictive).
[24] Manchikanti, Ex. A, at 1.

rate.[25] Consequently, the National Institute of Drug Abuse attributes the opioid crises to Defendants' successful marketing campaign.[26] Each Manufacturing Defendant spent, and continues to spend large sums of money to promote the benefits of opioids for non-cancer moderate pain while trivializing or even denying their risks.

14. The Manufacturing Defendants' promotional messages deviated substantially from any approved labeling of the drugs and caused prescribing physicians and consuming patients to underappreciate the health risks, and to overestimate the benefits of opioids.

15. Contrary to the language of their drugs' labels, Defendants falsely and misleadingly, in their marketing: (1) downplayed the serious risk of addiction; (2) promoted and exaggerated the concept of "pseudoaddiction" thereby advocating that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction.

16. Manufacturing Defendants disseminated these falsehoods through ads, sales representatives, and/or hand-picked physicians who supported Defendants'

[25] CDC/NCHS, *National Vital Statistics System, Mortality*, CDC Wonder, Atlanta, Ga: US Department of Health and Human Services, 2017, *available at https://wonder.cdc.gov.*
[26] *See id.*

message. Sales representatives, working at Manufacturing Defendants' behest, promoted highly addictive opioids through souvenirs and toys including, but not limited to, opioid brand-bearing stuffed plush toys, dolls, coffee cups, fanny packs, water bottles, notepads, pens, refrigerator magnets, clocks, letter openers, rulers, daytime planners, bags, puzzles, posters, hand-held calculators, clipboards, highlighters, flashlights, key chains, clothing, reflex mallets, and mock-ups of the United States Constitution.

17. Defendants also used third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups").

18. Manufacturing Defendants worked with KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Through their individual and concerted efforts, Defendants convinced doctors that instead of being addictive and unsafe for long-term use in most circumstances, opioids were *required* in the compassionate treatment of chronic pain, which Defendants termed an epidemic in America.

19. Manufacturing Defendants' aggressive marketing of opioids for chronic pain is "based on unsound science and blatant misinformation, and accompanied by the dangerous assumptions that opioids are highly effective and safe, and devoid of adverse events when prescribed by physicians."[27] Nevertheless, Defendants' marketing was effective and, by 2011, there were 136.7 million prescriptions for hydrocodone alone, with all opioids exceeding 238 million.[28] Data demonstrates that "[o]ver 90% of patients received opioids for chronic pain management."[29]

20. Essentially each Defendant ignored science and consumer health for profits. Defendants' efforts were so successful that opioids are now the most prescribed class of drugs generating $11 billion in revenue for drug companies in 2014 alone. Sales for Purdue's OxyContin grew from $48 million in 1996 to $1.1 billion in 2000 after it successfully and aggressively marketed and promoted its opioid.[30] In fact, OxyContin was a "leading drug of abuse" by 2004 through its availability.[31] Even after Purdue reached a $600 million federal settlement in 2007, the settlement failed to impact what is a "$13-billion-a-year opioid industry."[32]

[27] Manchikanti, Ex. A, at 1-4.
[28] *Id.*
[29] *Id.* at 19.
[30] Art Van Zee, M.D., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. Public Health 221, Feb. 2009, at 1, attached hereto as Exhibit B.
[31] Zee, *supra*.
[32] Rebecca L. Haffajee, J.D., Ph.D., M.P.H. and Michelle M. Mello, J.D., Ph.D., *Drug Companies' Liability for the Opioid Epidemic*, N. Engl. J. Med., Dec. 14, 2017, at 2305.

21. Defendants' efforts to promote prescription opioids to consumers as being more effective and less dangerous than they genuinely are has worked all too well. Even today, most parents surveyed believe that prescription opioids are the best post-surgical pain treatment for their kids when in fact, prescription opioids are the most addictive option and work no better in easing post-surgical pain than a number of safer treatments.[33]

22. The Distributor Defendants were not standing by idly while Marketing Defendants were peddling their opioids to physicians and consumers. Cardinal, AmerisourceBergen, and McKesson ("Distributor Defendants") are three of the largest opioid distributors in the United States. Distributor Defendants purchased opioids from Manufacturing Defendants herein and sold them to pharmacies throughout the Cities and Counties. Distributor Defendants function as "trusted partners" with Manufacturing Defendants in maximizing market share and success of pharmaceutical products. AmerisourceBergen states on its website that it is "[a] trusted partner [to manufacturers] in the commercialization process" and works with manufacturers "to optimize each stage − and each decision − along the product lifecycle."[34] McKesson claims that it works in partnership with manufacturers "to

[33] The American Society of Anesthesiologists. (2019, Jan. 27). *Parents worried about risks, but still think opioids are best for kids' pain relief, nationwide survey shows*. https://www.asahq.org/about-asa/newsroom/news-releases/2019/01/physaneswk19-news-release.
[34] AmerisourceBergen, "Brand and Specialty Manufacturer Solutions," https://www.amerisourcebergen.com/abcnew/solutions-manufacturers/brand-and-specialty.

develop, market, and deliver pharmaceuticals to patients."[35] In fact, McKesson claims that its "health care informatics expertise" allows it to provide manufacturers with "painstaking market research" to help manufacturers develop and refine their "product launch and market penetration strategy."[36] Cardinal Heath likewise advertises itself as a "consultative partner" to pharmaceutical manufacturers.[37]

23. Distributor Defendants promote themselves as partners and resources for pharmaceutical manufacturers in "pharmacovigilance," representing that they can "detect, assess, and monitor [ ] therapies throughout the patient journey."[38] Distributor Defendants like Cardinal Health provide Risk Evaluation and Mitigation Strategy (REMS) programs that "design [ ] and maintain [ ] registries of prescribers, pharmacies, distributors, and patients" and "assess [whether] patients are receiving and understanding medication guides."[39] Cardinal Health even advertises that it can help pharmaceutical manufacturers "ensure the highest level of patient touch by providing high-quality clinical services during therapy."[40] These Risk Evaluation

[35] McKesson, "Pharmaceutical Manufacturers: Better Partnerships, Better Heath," http://www.mckesson.com/pharmaceutical-manufacturers/.
[36] McKesson, "Health Care Informatics for Manufacturers," http://www.mckesson.com/manufacturers/health-care-informatics/.
[37] Cardinal Health, *Pharmaceutical Manufacturer*, http://www.cardinalhealth.com/en/services/manufacturer/pharma-manufacturer.html.
[38] Cardinal Health, *Pharmacovigilance and Medical Information*, http://www.cardinalhealth.com/en/services/manufacturer/pharma-manufacturer/cardinal-health-specialty-solutions/patient-solutions/access-and-patient-support/access-and-adherence/pharmacovigilance.html.
[39] Cardinal Health, *Risk Evaluation and Mitigation Strategy: Ensure the Specific Safety Needs of Your Therapy Are Met*, http://www.cardinalhealth.com/en/services/manufacturer/pharma-manufacturer/cardinal-health-specialty-solutions/patient-solutions/access-and-patient-support/access-and-adherence/rems.html.
[40] Cardinal Health, *Patient Centric Clinical Solutions*, http://www.cardinalhealth.com/en/services/manufacturer/pharma-manufacturer/cardinal-health-specialty-solutions/patient-solutions/access-and-patient-support/access-and-adherence/clinical-services.html.

and Mitigation Strategies require, among other things, that the Distributor Defendants provide through the chain of distribution a plain-English medication guide delivered to each patient that describes the serious risks of taking the prescription drug. This duty of the Distributor Defendants is not mitigated by the prescribing doctor.

24. Distributor Defendants have acknowledged and undertaken a duty to prevent prescription drug diversion and abuse based on their unique role in the opioid supply chain.[41] Distributor Defendants laud on their website their ability to detect and prevent prescription drug diversion to improper purposes. AmerisourceBergen claims it uses "complex algorithms [that] identify and stop orders that are deemed to be suspicious."[42] And Cardinal Health claims it uses a "state-of-the-art, constantly adaptive system to combat opioid diversion."[43]

25. Despite the alarming and suspicious rise in the number of opioids ordered by retailers in the Cities and Counties and Distributor Defendants self-claimed duty to stop suspicious opioid orders, Distributor Defendants simply continued to flood of opioids into the Cities and Counties. In continuing to

[41] Charles Ornstein, *Drug Distributors Penalized for Turning Blind Eye in Opioid Epidemic*, APR, Health News, Jan. 27, 2017; Letter from Pete Slone, Senior Vice President, Public Affairs, of McKesson, to The Honorable Chris Christie dated October 31, 2017; AmerisourceBergen Foundation, *AmerisourceBergen Foundation Launches Municipal Support Program to Help Combat Opioid Abuse*, Dec. 14, 2017 press release; Cardinal Health, *Cardinal Health's Commitment to Opioid Anti-Diversion, Education and Misuse Prevention,* www.cardinalhealth.com; Cardinal Health, *No Demographic Group, supra.*.

[42] *Id.*

[43] Cardinal Health, *Opioid Action Program: Reclaiming our Communities*, www.cardinalhealth.com.

oversupply opioids in the Cities and Counties, Distributor Defendants put their partnership with pharmaceutical manufacturers − to increase market penetration − above their obligations to secure the opioid supply claim. Manufacturing Defendants and Distributor Defendants worked hand and glove to glut the Cities and Counties with more opioids than could possibly be consumed for therapeutic purposes, resulting in an opioid prescription rate in the Cities and Counties that remains well above the already insupportable national rate. Each Defendant disregarded its legal duty to ensure that not only that opioids were safe and effective, but that they were being prescribed for a valid medical purpose.

26. Pharmacy Defendant CVS acted as both a distributor and pharmacy. CVS played a dual role in creating this epidemic. Its operations distributed the opioids through its vast networks to their pharmacies, or pharmacy mailing distribution centers, and then dispensed the drugs to its customers either through delivery or over the pharmacy counter. CVS was well-positioned to see how widespread the problem was and the inordinate amount of opioids flooding the Cities and Counties and point of first injury. CVS also had a duty under state and federal law to report any suspected diversions of opioids.

27. As a direct and foreseeable consequence of Defendants' misrepresentations and misleading marketing campaign to the Cities and Counties physicians and residents regarding the safety and efficacy of using opioids for

chronic non-cancer pain that resulted in an oversupply of opioids, the Cities and Counties have spent and continue to spend large sums of money combatting the public health crisis.

28. The money the Cities and Counties have spent comes directly from its taxpayers. These taxpayers include physicians in the Cities and Counties, who passed on Defendants' misleading safety and efficacy information and prescribed more opioids to taxpaying residents in the Cities and Counties. These taxpayers also included Plaintiffs' residents who either suffered the addictive effects of consuming opioids or overdosed using Defendants' opioids that had been over-prescribed and over-supplied to the Cities and Counties as intended by Defendants herein. Thus, this group of Plaintiffs' residents have suffered not only injury to property, but also bodily injury, as a result of Defendants' misconduct in the false promotion and/or over-supply of prescription opioids.

29. The Cities and Counties have spent and continue to spend large sums of money combatting the opioid crisis created by Defendants' negligent and fraudulent marketing campaign. Across the country, including Montana, increased opioid prescribing has caused and continues to cause an increase in overdoses and death. Defendants tracked the CDC data and knew that the more they promoted opioid prescribing and distributed more opioids that non-therapeutic outcomes, such as overdose, addiction, and criminality would occur. By 2010, enough opioids had

been sold to medicate every American adult with a typical dose of 5 mg of hydrocodone every 4 hours for 1 month.[44] The increased use of opioids has contributed to the increased rate of overdose deaths and nonmedical use with the varying rates of sales in each state impacting the outcomes in each state.[45] "Given that 3% of physicians accounted for 62% of the [opioids] prescribed in one study, the proliferation of high-volume prescribers can have a large impact on state use of [opioids] and overdose death rates."[46] Not surprisingly, "[l]arge increases in overdoses involving the types of drugs sold by illegitimate pain clinics (i.e., 'pill mills') have been reported in Florida and Texas."[47] In the City of Great Falls, which is located in Cascade County, the prescription rate per 100 people in 2016 was 97.2, which means that almost every man, woman, and child in the County could have had at least one bottle of opioids.[48] And in 2016, there were approximately 18 – 19.9 deaths per 100,000 people reported from drug overdoses.[49] In Anaconda-Deer Lodge County, the prescription rate per 100 people in 2016 was 96, which means that almost every man, woman, and child could have had at least one bottle of opioids.[50] In 2016, there were over 30 deaths per 100,000 people reported from drug overdoses

[44] Center for Disease Control, *Vital Signs: Overdoses of Prescription Opioid Pain Relievers – United States, 1999-2008*, Morbidity and Mortality Weekly Report (MMWR), Nov. 4, 2011.
[45] *Id.*
[46] *Id.*
[47] *Id.*
[48] Center for Disease Control, *available at* https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html.
[49] Center for Disease Control, *available at* https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality.
[50] Center for Disease Control, *available at* https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html.

in Anaconda-Deer Lodge County.[51] In Lake County, thousands of prescriptions were written for opioids from 2015 – 2016,[52] and from 2015 - 2016, there were 24 – 25.9 deaths per 100,000 people reported from drug overdoses in Lake County.[53] In the City of Missoula, which is located in Missoula County, thousands of prescriptions were written for opioids from 2015 – 2016,[54] and from 2015 - 2016, there were 18 – 19.9 deaths per 100,000 people reported from drug overdoses.[55] A substantial number of those overdose deaths in the Cities and Counties were a result, in whole or in part, of opioid ingestion. Defendants' marketing misconduct, as well as Defendants' efforts to sell more prescription opioids than can be consumed therapeutically, were natural and foreseeable causes of overdose deaths and injuries in the Cities and Counties.

30. But for Defendants' deceptive marketing scheme that changed the way physicians prescribe opioids, coupled with the systemic undermining of quotas and institutional controls as well as the failure to report suspicious orders by both the Marketing and Distributor Defendants, the number of opioids would not have tripled or quadrupled thereby directly giving rise to the opioid epidemic – the costs of which have resulted in Plaintiffs' alleged injuries.

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[51] Center for Disease Control, *available at* https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality.
[52] https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html; https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality.
[53] Center for Disease Control, *available at* https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality.
[54] https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html; https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality.
[55] Center for Disease Control, *available at* https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality.

31. As a direct and foreseeable consequence of Defendants' conduct described regarding prescription opioids, Plaintiffs have committed and continue to commit resources to provide and pay additional health care, law enforcement, social services, public assistance, pharmaceutical care and other services necessary for its residents.

II. VENUE AND JURISDICTION

32. Venue is proper in the United States District Court for the District of Montana, Great Falls Division, because a substantial part of the events or omissions giving rise to this claim occurred in the City of Great Falls. Mont. Code Ann. §§25-2-122(1)(b); 25-2-115.

33. Federal subject matter jurisdiction is based upon 28 U.S.C. § 1332 because there is complete diversity among Plaintiffs and Defendants in each of the constituent actions and the amount in controversy exceeds $75,000, exclusive of interest and costs.

34. The Court has specific jurisdiction over all Defendants as their activities were directed toward Montana, and injuries complained of herein resulting from their activities. Mont. R. Civ. P. 4B(1). Each Defendant has a substantial connection with Montana and the requisite minimum contacts with Montana necessary to constitutionally permit the Court to exercise jurisdiction. *See id.*

III. PARTIES

A. Plaintiffs

35. This action is brought for and on behalf of the City of Great Falls, Montana, which provides a wide range of services on behalf of its residents, including services for families and children, public health, public assistance, law enforcement, and emergency care.

36. This action is brought for and on behalf of the County of Anaconda-Deer Lodge, Montana, which provides a wide range of services on behalf of its residents, including services for families and children, public health, public assistance, law enforcement, and emergency care.

37. This action is brought for and on behalf of the County of Lake, Montana, which provides a wide range of services on behalf of its residents, including services for families and children, public health, public assistance, law enforcement, and emergency care.

38. This action is brought for and on behalf of the City of Missoula, Montana, which provides a wide range of services on behalf of its residents, including services for families and children, public health, public assistance, law enforcement, and emergency care.

B. Defendants

39. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut. THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company are hereinafter referred to as "Purdue").

40. Upon information and belief, Purdue manufactures, promotes, sells, and distributes opioids in the U.S. and the Cities and Counties. Purdue's opioid drug, OxyContin, is one of the most addictive and abused prescription drugs in American history. Purdue has promoted opioids throughout the United States and in the Cities and Counties.

41. CEPHALON, INC. (hereinafter "Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Upon information and belief, Cephalon, Inc. manufactures, promotes, sells, and distributes opioids in the U.S. and in the Cities and Counties.

42. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICALS, INC. is a wholly owned subsidiary of JOHNSON &

JOHNSON. JOHNSON & JOHNSON ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are hereinafter referred to as "Janssen").

43. Upon information and belief, Janssen manufactures, promotes, sells, and distributes opioids in the U.S. and in the Cities and Counties.

44. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS, INC., a wholly owned subsidiary of ENDO HEALTH SOLUTIONS INC., is a Delaware corporation with its principal place of business in

Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals, Inc. are hereinafter referred to as "Endo").

45. Upon information and belief, Endo develops, markets, and sells opioid drugs in the U.S. and in the Cities and Counties. Endo also manufactures, sells, and distributes generic opioids in the U.S. and the Cities and Counties, by itself and through its subsidiary, Par Pharmaceutical, Inc., successor-by-merger to Qualitest Pharmaceuticals, Inc.

46. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to ALLERGAN FINANCE, LLC as of October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Allergan plc f/k/a Actavis plc. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC. is a Delaware corporation with its principal place of business in New Jersey. Each of these defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States (Allergan plc f/k/a Actavis plc,

Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. are hereinafter referred to as "Actavis").

47. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

48. Upon information and belief, Actavis manufactures, promotes, sells, and distributes opioids in the U.S. and in the Cities and Counties.

49. AMERISOURCEBERGEN CORPORATION is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. AMERISOURCEBERGEN DRUG CORPORATION is a Delaware corporation with its principal place of business in Conshohocken, Pennsylvania (AmerisourceBergen Corporation and AmerisourceBergen Drug Corporation are hereinafter referred to as "Amerisource").

50. Upon information and belief, Amerisource does substantial business in Montana and is a pharmaceutical distributor licensed to do business in Montana. Amerisource distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including Montana and the Cities and Counties.

51. CARDINAL HEALTH, INC. is an Ohio corporation with its principal place of business in Dublin, Ohio. CARDINAL HEALTH 110, LLC, a wholly-owned subsidiary of CARDINAL HEALTH, INC., is a Delaware limited liability company with its principal place of business in Dublin, Ohio (Cardinal Health, Inc. and Cardinal Health 110, LLC are hereinafter referred to as "Cardinal").

52. Upon information and belief, Cardinal does substantial business in Montana and is a pharmaceutical distributor licensed to do business in Montana. Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including Montana and the Cities and Counties.

53. MCKESSON CORPORATION (hereinafter "McKesson") is a Delaware corporation with its principal place of business in San Francisco, California.

54. Upon information and belief, McKesson is a pharmaceutical distributor licensed to do business in Montana. McKesson distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including Montana and the Cities and Counties.

55. CVS HEALTH CORPORATION is a Delaware corporation with its principal place of business in Woonsocket, Rhode Island. CVS INDIANA, L.L.C., a wholly owned subsidiary of CVS HEALTH CORPORATION, is an Indiana limited liability company with its principal place of business in Woonsocket, Rhode

Island. CVS PHARMACY, INC., a wholly owned subsidiary of CVS HEALTH CORPORATION, is a Rhode Island corporation with its principal place of business in Woonsocket, Rhode Island (CVS Health Corporation, CVS Indiana, L.L.C., and CVS Pharmacy, Inc. are hereinafter referred to as "CVS").

56. Upon information and belief, CVS is a pharmaceutical distributor licensed to do business in Montana. CVS distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including Montana and the Cities and Counties.

57. The Cities and Counties lack information sufficient to specifically identify the true names or capacities, whether individual, corporate or otherwise, of Defendants sued herein under the fictitious names DOES 1 through 100 inclusive. The Cities and Counties will amend this Complaint to show their true names and capacities if and when they are ascertained. The Cities and Counties are informed and believe, and on such information and belief allege, that each of the Defendants named as a DOE has engaged in conduct that contributed to cause events and occurrences alleged in this Complaint and, as such, shares liability for at least some part of the relief sought herein.

IV. FACTUAL ALLEGATIONS

58. Before the 1990s, generally accepted standards of medical practice dictated that opioids should be used only for short-term acute pain – pain relating to

recovery from surgery or for cancer or palliative (end-of-life) care. Using opioids for chronic pain was discouraged or even prohibited because there was a lack of evidence that opioids improved patients' ability to overcome pain and function. Instead the evidence demonstrated that patients developed tolerance to opioids over time, which increased the risk of addiction and other side effects.

59. After the 1990s, Defendants dramatically changed doctors' views regarding opioids through a well-funded deceptive marketing scheme. Defendants were so successful that, according to the National Safety Council, 74% of ***all*** doctors prescribe opioids for chronic back pain and 55% prescribe opioids for dental pain, "neither of which is appropriate in most cases."[56] And 99% of doctors are prescribing them for longer than the three-day recommended period as recommended by the CDC.[57] Twenty-three percent prescribe at least a month's worth of opioids and evidence shows that just 30 days of usage can cause brain damage.[58]

60. Each Defendant used direct marketing and unbranded advertising (*i.e.*, advertising that promotes opioid use generally but does not name a specific opioid) disseminated by seemingly independent third parties to spread false and deceptive

[56] National Safety Council, *NSC Poll: 99% of Doctors Prescribe Highly-Addictive Opioids Longer than CDC Recommends*, 2017 (The NSC was founded in 1913 and chartered by Congress and is a non-profit organization whose mission is to save lives by preventing injuries and deaths at work, in homes, and in the communities through leadership, research, education, and advocacy).
[57] *Id.*
[58] *Id.*

statements about the risks and benefits of long-term opioid use. Defendants advocated the widespread use of opioids for chronic pain even though it contravened the "cardinal principles of medical intervention – that there be compelling evidence of the benefit of a therapy prior to its large-scale use."[59]

A. Defendants Used Multiple Avenues to Disseminate their False and Deceptive Statements about Opioids.

61. Defendants spread their false and deceptive statements by (1) marketing their branded opioids directly to doctors treating patients residing in the Cities and Counties and the Cities and Counties patients themselves and (2) deploying so-called unbiased and independent third parties to the Cities and Counties.

1. Defendants Spread and Continue to Spread Their False and Deceptive Statements Through Direct Marketing of Their Branded Opioids.

62. Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Manufacturing Defendant conducted advertising campaigns touting the purported benefits of their branded drugs. For example, Purdue spent $200 million promoting and marketing OxyContin in various forms.[60] Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001, including $8.3 million by Purdue, $4.9 million by Janssen, and $1 million by Endo.

[59] Manchikanti, Ex. A, at 2.
[60] Zee, Ex. B, at 2.

63. A number of Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website, www.opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like a construction worker and chef, implying that the drug would provide long-term pain-relief and functional improvement.

64. Purdue also ran a series of ads, called "pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Second, each Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs.

65. Defendants devoted massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent $154 million on detailing branded opioids to doctors, including $108 million by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis.

66. Defendants sent their sales representatives to prescribers based on their specialties and prescribing habits obtained from sales data through IMS Health. Defendants used this data to monitor, and thereby target, specific physicians through

the initial and renewal prescribing rates. To ensure that their sales representatives were properly incentivized, Defendants motivated them through bonuses. In 2001, Purdue paid $20 million in "sales incentive bonuses" to its sales representatives.[61]

67. Defendants also utilized "influence mapping" to use decile rankings or similar breakdowns to identify high-volume prescribers. The underlying strategy was that detailers would have the biggest sales impact on high-volume prescribers. For example, Endo identified prescribers representing 30% of its nationwide sales volume and planned sales visits three times per month to these physicians. These detailers visited physicians across the nation, including physicians in the Cities and Counties. Defendants also had access to data from IMS Health, which provides Defendants specific details about which medications physicians prescribe and how frequently they do so. This data was collected from more than 50% of the pharmacies in the United States, which would inform Defendants which doctors to target to convince them to prescribe more opioids or to start prescribing opioids instead of the medications they had been prescribing.

68. Another manner in which Defendants expanded their sales was to target prescribers in individual zip codes and local boundaries. Defendants would send a detailer based on ease of in-person access and the likelihood of convincing the physician to prescribe a higher number of opioids and at higher doses.

[61] Zee, Ex. B, at 2.

69. As part and parcel of their detailing of opioids to physicians, Purdue trained its sales representatives to inform physicians that the risk of addiction was "less than one percent" even though studies demonstrated that there was a high incidence of drug abuse associated with prescription opioid use for chronic pain.[62]

70. As Defendants' marketing efforts grew, they targeted nurse practitioners and physician assistants who, a 2012 Endo business plan noted, were "share acquisition" opportunities because they were more responsive than physicians to details and wrote most of their prescriptions without a physician consult.

71. Studies demonstrate that visits from sales representatives influence the prescribing practices of residents and physicians by curtailing the prescription of generic drugs and rapidly expanding the prescription of new drugs, such as opioids for chronic pain.[63] In a population-based county-level analysis of drug company marketing of prescription opioids – a study which included ***all*** U.S. counties – the marketing of opioid products to physicians was associated with both increased opioid prescribing and elevated mortality from overdoses.[64] (Emphasis added.)

[62] Zee, Ex. B, at 3.
[63] *Id.* at 6.
[64] Hadland, S.E., Rivera-Aguirre, A., Marshall, B.D.L., Cerdá, M. (Jan. 2019). Association of Pharmaceutical Industry Marketing of Opioid Products with Mortality From Opioid-Related Overdoses." *The Journal of American Medical Association (JAMA) Network Open.* DOI:10.1001/jamanetworkopen.2018.6007

72. Defendants also paid doctors to serve on speakers' bureaus, to attend programs, and for meals.[65] In 2017, Dr. Hadland identified some of these payments from pharmaceutical companies to physicians prescribing opioids.[66] It was the first time "industry payments to physicians related to opioid marketing" could be collated because of the "Open Payments program database" authorized under the "Physician Payments Sunshine Act."[67] Dr. Hadland explained that it was the first large-scale examination of these payments.[68]

73. One statistic Dr. Hadland gleaned from the data is that nearly 1 in 5 family physicians in 2013, out of 108,971 active family physicians, received an opioid-related payment.[69] After culling through the Open Payments program database, Dr. Hadland concluded that "[f]inancial transfers" from pharmaceutical companies to physicians prescribing opioids "were substantial and widespread and may be increasing in number and value."[70]

74. Some of the financial transfers most likely involved speaker programs, which provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the

[65] *See* Scott E. Hadland, M.D., M.P.H, M.S., *Industry Payments to Physicians for Opioid Products, 2013-2015*, 107 Am. J of Pub. Health 9, Sept. 2017, attached hereto as Exhibit C.
[66] *See id.* at 1493.
[67] *Id.*
[68] *Id.* at 1495.
[69] Hadland, Ex. C, at 1494.
[70] *Id.* at 1495.

speaker to his or her peers. These speakers gave the false impression that they were providing unbiased and medically accurate presentations when they were, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

75. Defendants employed the same marketing plans, strategies, and messages in and around the Cities and Counties in Montana, as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are accurately and consistently delivered across marketing channels and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

2. Defendants Used a Diverse Group of Seemingly Independent Third Parties to Spread False and Deceptive Statements about the Risks and Benefits of Opioids.

76. Defendants also deceptively marketed opioids in and around the Cities and Counties through unbranded advertising. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled the

deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for treating chronic pain. Unbranded advertising also avoided regulatory scrutiny because Defendants did not have to submit it to the FDA, and therefore it was not reviewed by the FDA. But it is illegal for a drug company to distribute materials that exclude contrary evidence or information about the drug's safety or efficacy that "clearly cannot be supported by the results of the study."[71] Moreover, a drug company cannot compare or suggest that its "drug is safer or more effective than another drug…when it has not been demonstrated to be safer or more effective in such particular by substantial evidence of substantial clinical experience."[72] It is therefore Defendants' responsibility to ensure that not only is its label accurate and complete, but that any and all materials they distribute is accurate and complete.[73]

77. Defendants' deceptive unbranded marketing often contradicted their branded materials. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	**Opana ER Advertisement (Branded)**
	"All patients treated with opioids require careful

[71] 21 C.F.R. § 99.101(a)(4).
[72] 21 C.F.R. § 202.1 (e)(6)(ii).
[73] *See* 21 C.F.R. § 201.56 (providing general requirements for prescription drug labeling); 21 C.F.R. § 314.70(c)(6)(iii)(A-C) (providing for changes to labels that strengthen precautions, warnings, or adverse reactions, as well as statements about drug abuse, dependence, or overdosage); *see also Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that a drug company bears responsibility for the content of its drug label at all times).

"People who take opioids **as prescribed usually do not become addicted**."	monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."

78. Drug companies that make, market, and distribute opioids are generally subject to rules requiring truthful marketing of prescription drugs. A drug company's branded marketing, which identifies and promotes a specific drug, must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.[74]

79. This framework ensures that drug companies, which are best suited to understand the properties and effect of their drugs, bear the responsibility of providing accurate information so that prescribers and users can assess the risks and benefits of the drugs.

80. Defendants did not follow this framework in assisting, creating, and/or distributing third-party publications that included warnings and instructions either mandated by the FDA-required drug labels or that described the risks and benefits known to Defendants. The publications either failed to disclose the risk of addiction and misuse or affirmatively denied the risk of addiction. The publications also

[74] 21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a); 202.1(e)(3); 202.1(e)(6).

"appeared" to be independent third-party materials that had the effect of carrying more weight and credibility to convince physicians that opioids were safe for chronic pain.

a. Defendants Utilized Treatment Guidelines to Promote their Deception.

81. Defendants used treatment guidelines to normalize the use of opioids for chronic pain. Doctors, especially general practitioners and family doctors, rely upon treatment guidelines when faced with patients complaining of chronic pain. Scientific literature references treatment guidelines in making its conclusions and third-party payers use treatment guidelines to determine coverage. Even Endo's internal documents indicate that sales representatives discussed treatment guidelines with doctors during individual sales visits.

1. The FSMB Wrote or Sponsored Misleading and Deceptive Guidelines.

82. Headquartered in Euless, Texas, the Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline doctors. The FSMB finances opioid and pain-specific programs through grants from Defendants.

83. In 1998, the FSMB developed *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which was produced in collaboration with pharmaceutical companies. The FSMB guidelines instructed that opioids were "essential" for the treatment of chronic pain, even as a first prescription option.

84. A book adapted from the 2007 FSMB guidelines, *Responsible Opioid Prescribing: A Physician's Guide* ("*Opioid Prescribing*"), released March 1, 2009 makes these same claims. *Opioid Prescribing* was supported by a consortium of pharmaceutical companies and Front Groups with an interest in ensuring that "effective" pain management included the use of opioids.

85. The author of *Opioid Prescribing*, Scott Fishman, M.D., chaired the board and was past president of the American Pain Foundation and served as president of the American Academy of Pain Medicine and served on the board of directors. *Opioid Prescribing* was sponsored by the Alliance of State Pain Initiatives, Federation of State Medical Boards, and the University of Wisconsin School of Medicine and Public Health.[75]

[75] Scott M. Fishman, M.D., *Responsible Opioid Prescribing, A Physician's Guide*, FSMB Foundation, Waterford Life Sciences, 2009.

86. Dr. Fishman was a paid consultant to Cephalon and Eli Lilly. Dr. Fishman was also a paid consultant, on the Speakers' Bureau, and part of the research support for Endo, Merck, Janssen, Pfizer and Purdue.[76]

87. *Opioid Prescribing* was designed for continued medical education ("CME") in which a physician had to read the book, complete questions, and fulfill administrative steps to receive 7.5 hours of credit. The first page of *Opioid Prescribing* specifically states that opioids are the "drugs of choice" and "essential in the treatment of persons with chronic non-cancer pain" and that the CME will inform physicians about the laws and regulations governing the prescribing of opioids for pain control.[77] It also specifically teaches physicians how to protect their practices from unwarranted federal scrutiny.[78]

88. *Opioid Prescribing* marketed "[o]pioid analgesics" as the "drugs of choice for the management of moderate to severe pain… [which] may be *essential* in the treatment of persons with chronic non-cancer pain."[79] The goal was to "change patient care, medical knowledge, practice-based learning, interpersonal and communication skills, and professionalism…."[80] The argument was that opioids were "underutilized" despite their "effectiveness."[81] The truth, known to Dr.

[76] Fishman, *supra.*
[77] *Id.*
[78] Fishman, *supra.*
[79] *Id.* at i.
[80] *Id.*
[81] *Id.*

Fishman and Defendants herein, was that using opioids "for other than legitimate medical purposes pose[d] a threat to the individual and society," posed high risks for overdose and addiction, and remained unproven as safe and effective for the long-term treatment of non-cancer pain.[82]

89. It was even conveyed to doctors that undertreating pain would be officially disciplined whereas doctors prescribing opioids for chronic pain would not be disciplined. *Opioid Prescribing* described a case in which a physician was sued for "elder abuse" and the jury awarded $1.5 million to the Plaintiffs as an example of a physician that had been "successfully sued for not treating pain aggressively."[83] *Opioid Prescribing* cautioned that "these legal precedents sound a warning that there are risks associated with under-treating."[84] In actuality, it was a threat that doctors would be punished if they *failed* to prescribe opioids to patients who complained about pain. That teaching has held true given that according to the National Safety Council, 67% of doctors prescribe opioids, in part, based on a patient's expectations.[85] Moreover, approximately 74% of doctors incorrectly believe morphine and oxycodone are the most effective ways to treat pain even though

[82] Fishman, *supra* at 6, 9.
[83] *Id.* at 28.
[84] Fishman, *supra.*
[85] National Safety Council, *supra*.

research shows that over-the-counter medications such as ibuprofen and acetaminophen are the most effective pain relief for acute pain.[86]

90. Defendants also allayed any concerns doctors may have about patients exhibiting addictive behavior by highlighting the now debunked myth of "pseudoaddiction." Dr. Fishman described pseudoaddiction as a sign that patients were receiving an inadequate dose to obtain pain relief, not as a sign that the patient was exhibiting drug-seeking or addictive behavior.[87]

91. *Prescribing Opioids* taught physicians that the following signs were evidence of "pseudoaddiction" and *not* drug seeking behavior or signs of addiction so long as prescribing additional opioids resolves the pain:

- Requesting analgesics by name;
- Demanding or manipulative behavior,
- Clock watching;
- Taking opioid drugs for an extended period;
- Obtaining opioid drugs from more than one physician; and
- Hoarding opioids.[88]

92. Indeed, the types of behaviors that Dr. Fishman posed as "MORE indicative of addiction" included:

[86] Fishman, *supra.*
[87] *Id* at 62.
[88] Fishman, *supra.*

- Stealing money to obtain drugs;
- Performing sex for drugs;
- Stealing drugs from others;
- Prostituting others for money to obtain drugs;
- Prescription forgery; and
- Selling prescription drugs.[89]

93. Certainly by the time a patient is performing sex for drugs, the patient has long been addicted and exhibited addictive behavior that was ignored by physicians at the explicit direction of Defendants. This conclusion is supported by the American Psychiatric Association.

94. In the DSM-IV, addiction is "manifested" by three (or more) of the following in a 12-month period, including:

a) Tolerance described as:

A need for markedly increased amounts of the substance to achieve intoxication or the desired effect

or

Markedly diminished effect with continued use of the same amount of the substance;

b) Withdrawal manifested by:

The characteristic withdrawal syndrome for the substance

[89] *Id.* at 63.

or

The same (or closely related) substance is taken to relieve or avoid withdrawal symptoms;

c) The substance is taken in larger amounts or over a longer period than intended; and

d) Spending a great deal of time to obtain the substance, such as visiting multiple doctors or driving long distances.[90]

95. According to Defendants, as seen in *Prescribing Opioids* and other publications, signs of addiction as defined by the American Psychiatric Association are not signs of addiction, but of pseudoaddiction that justifies taking *more* opioids for a longer period of time.

96. The reason not to discontinue the use of opioids – indeed, the foundation upon which Defendants built its opioid empire – was "the undertreatment of pain."[91] *Opioid Prescribing* claimed the undertreatment of pain has "been recognized as a public health crisis for decades. The cost of human suffering is immeasurable. Turning away patients in pain simply is not an option."[92] However, according to Dr. Donald Treater, medical advisor at The National Safety Council: "Opioids do not kill pain; they kill people."[93]

[90] American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Ed., Washington, D.C., American Psychiatric Assoc., 2000.
[91] Fishman, *supra*, at 105.
[92] *Id.*; *see also id.* at 80 (stating that efforts have been made to reduce the undertreatment or non-treatment of pain in children, the elderly, and in other vulnerable patient populations).
[93] National Safety Council, *supra*.

97. *Prescribing Opioids* acknowledged that by 2005, more than 10 million Americans were abusing prescription drugs, which is more than the combined number of people abusing cocaine, heroin, hallucinogens, and inhalants combined.[94] It also acknowledged that prescription opioids are associated with more overdose deaths than cocaine and heroin combined.[95] Yet the book then cautioned that the "undertreatment" of non-cancer pain was a public health crisis of equal importance that justified more opioid prescribing.

98. Under the guise of addressing "legitimate cause of undertreated pain" that "patients and advocates have been pushing to address,"[96] Defendants tailored opioid marketing campaigns to affect children and the elderly. The Defendants made significant efforts to promote more opioid prescribing for "untreated or undertreated pain in children, older patients, and in all other vulnerable patient populations."[97]

99. Defendants also taught physicians that "[p]ain is what the patient says it is" and that a physician "cannot measure or even confirm the pain that a patient is experiencing."[98] As such, "pain remains an untestable hypothesis."[99] Furthermore, "[p]atients should not be denied opioid medications except in light of clear evidence

[94] *Responsible Opioid Prescribing*, *supra*, at 6.
[95] *Id.*; *Prescribing Opioids* even recognized that "[b]ehind these figures lie millions of individual stories of personal tragedy: untimely death, fractures families, shattered dreams and wasted lives." *Id.* at 7.
[96] *Id.* at 8.
[97] Fishman, *supra*, at 8.
[98] *See id.* at 14.
[99] *Id.* at 13.

that such medications are harmful to the patient."[100] All in all, opioids would cure the "pain epidemic" facing Americans. And yet, chronic pain continues to be a problem facing Americans, as well as an opioid epidemic of addiction and death.

100. A total of 200,000 copies of *Opioid Prescribing*, which Dr. Fishman wrote for the FSMB, has been delivered to U.S. prescribers through 20 state medical boards, including Montana.[101] The FSMB earned approximately $250,000 from the sale. The FSMB website describes the book as the "leading continuing medication education (CME) activity for prescribers of opioid medications."

101. The guidelines for *Opioid Prescribing* were posted online for use and reliance by physicians throughout America, including but not limited to, those servicing patients in the Cities and Counties. State medical boards even encouraged physicians to buy the book and participate in the CME. The North Carolina Medical Board stated on its website that *Prescribing Opioids* "has been *widely used and supported* in the medical and regulatory communities as the leading continuing medical education (CME) activity for prescribers of opioid medications."[102] The website then informs physicians that a CME accompanies the book and directs them to the book and how to claim the CME. The CME taught physicians the "safe and

[100] *Id.* at 9.
[101] Scott M. Fishman, M.D., *Listening to Pain*, Oxford Univ. Press, 2012, at 135.
[102] North Carolina Medical Board, *FSMB Foundation Publishes Second Edition of Prescribing Book*, Forum Newsletter, July 31, 2012; *see also* University of Wisconsin School of Medicine and Public Health, Federation of State Medical Boards, *Responsible Opioid Prescribing – Book Helps Physicians Reduce Risk of Opioid Diversion and Abuse*, April 1, 2009 (describing the book and CME activity).

responsible prescribing of opioid medications and [was] aimed at improving prescriber training and counseling for patients while providing more thorough information on extended-release or long-acting (ER/LA) opioid products on the market."[103]

102. The impact of *Opioid Prescribing* was even studied through a survey sent to 12,666 licensed Georgia physicians six weeks after receiving the book.[104] The lead author was a member of FSMB.[105] A total of 508 physicians completed the online survey and of those, 82.1% rated the book either "very good" or "good" for improving care for their patients in pain.[106] Almost one-third (32.2%) claimed that they intended to make changes to their practice after reading the book.[107] Of note, 42.8% of solo practitioners and 41.6% of primary care providers were more likely to make changes to their practice than doctors in other areas.[108] Of the respondents, 57.7% said that the book was better than others with regard to prescribing opioids and on pain management.[109]

[103] North Carolina Medical Board, *FSMB Foundation Publishes Second Edition of Prescribing Book*, Forum Newsletter, July 31, 2012; *see also* University of Wisconsin School of Medicine and Public Health, Federation of State Medical Boards, *Responsible Opioid Prescribing – Book Helps Physicians Reduce Risk of Opioid Diversion and Abuse*, April 1, 2009 (describing the book and CME activity).
[104] A. Young, *Physician Survey Examining the Impact of an Educational Tool for Responsible Opioid Prescribing*, J. Opioid Management, Mar-Apr. 2012.
[105] *Id.*
[106] *Id.*
[107] *Id.*
[108] *Id.*
[109] *Id.*

103. *Opioid Prescribing* was therefore an effective tool that impacted specific doctors and their prescribing practices, as concluded by the study. Specifically, the study provided "insight into which physician population would be the most receptive to the type of information presented in Dr. Fishman's book" and that population was to "first target[] solo and primary care physicians."[110] Defendants found out that their educational efforts "significantly altered prescription practices."[111]

2. The Joint Commission also Spread Deceptive Information.

104. The Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") is a United States-based non-profit, tax-exempt organization that "accredits and certifies nearly 21,000 health care organizations and programs in the United States."[112] A majority of state governments recognize accreditation from the Joint Commission as a condition of licensure and for receiving Medicaid and Medicare reimbursements.[113] Providence Saint Joseph Medical Center in Lake County, Montana, St. Patrick Hospital in Missoula, Montana, and the Montana VA Healthcare System are accredited by and subscribe to the JCAHO.[114]

[110] Young, *supra.*
[111] *Id.*
[112] www.jointcommission.org.
[113] Anthony Anonimo, *Poppy Seed. Revealing the Roots of the Opioid Epidemic*, Trinity Mother Frances Health System, 2017, at 65.
[114] www.jointcommission.org

105. According to the JCAHO, it "continuously improve[s] health care for the public" and inspires health care organizations "to excel in providing safe and effective care of the highest quality and value."[115] The JCAHO is not independent, but has been influenced by Defendants and those Defendants used the JCAHO as a marketing shill to spread the misleading message that opioids are non-addictive and safe as a first-line analgesic to treat any complaint of pain.

106. In 2000, the JCAHO published *Pain Assessment and Management: An Organizational Approach* ("*Pain Assessment"*), which was paid for by Purdue and reviewed by June L. Dahl, Ph.D., who has worked for Abbott, Endo, and Purdue.[116]

107. The JCAHO mission statement on the inside cover page of the book explains that it aspires "to continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support the performance improvement in health care organizations."[117] One of its big achievements, however, is its endorsements of new pain management standards that underscored Defendants' fraudulent message.

108. JCAHO, with the help of the American Pain Society ("APS"), a Front Group, loosened pain management standards thereby allowing doctors to prescribe opioids for any complaint of pain. To that end, "[t]he Joint Commission recognize[d]

[115] www.jointcommission.org
[116] Joint Commission on Accreditation of Healthcare Organizations, *Pain Assessment and Management*, 2000.
[117] *Id.*

pain as a major, yet largely avoidable, problem…. [and] has expanded the scope of its pain management standards, which have been endorsed by the American Pain Society (APS), *to cover all pain scenarios in accredited health care organizations rather than limiting the scope to end-of-life care*."[118] (Emphasis added.)

109. *Pain Assessment* established the cornerstone of Defendants' message that "all pain scenarios" should be included in pain management practices.[119] It explained that "[p]ain is the most common reason individuals seek medical attention. According to the American Pain Society (APS), 50 million Americans are partially or totally disabled by pain."[120] "The conclusion? Pain is undertreated – despite the availability of effective pharmacologic and nonpharmacologic therapies. Why?"[121]

110. The answer is on the first page of *Pain Assessment*. There is a chronic pain epidemic. Chronic pain is undertreated. Chronic pain can be managed and even cured with opioids, which are safe and effective, according to *Pain Assessment*. And the JCAHO encouraged organizations to establish standards for recording and responding to patient pain reports and monitoring staff performance and compliance with those standards, so that a physician who did not agree with the JCAHO standards faced the specter of poor performance evaluations.[122]

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[118] *Pain Assessment, supra.*
[119] *Pain Assessment, supra*, at p. 1.
[120] *Id.*
[121] *Id.*
[122] *Pain Assessment, supra*, at 41-42.

111. According to *Pain Assessment*, the reasons healthcare professionals had not used opioids previously included: (1) inadequate knowledge of opioids pharmacology and pain therapy, (2) poor pain assessment practices, (3) unfounded concerns about regulatory oversight, and (4) fear of opioids' side effects such as tolerance and addiction.[123]

112. *Pain Assessment* asserted that few practitioners received adequate training in pain management in medical school or during their residency resulting in the failure to prescribe opioids or nonsteroidal anti-inflammatory drugs (NSAIDS) on a regular basis leaving patients without pain relief.[124] "[Many] health care professionals lack the knowledge and skills to manage pain effectively, and they fear the effects of treatment."[125] Too few health care systems make pain management a priority.[126] Some clinicians had "inaccurate and exaggerated concerns about addiction, tolerance, respiratory depression, and other opioid side effects, which lead them to be extremely cautious about the use of drugs."[127] Instead of expanding upon and explaining the risks of opioids, *Pain Assessment* states: "***This attitude prevails despite the fact there is no evidence that addiction is a signification issue when persons are given opioids for pain control***."[128] (Emphasis added). That claim of

[123] *Pain Assessment, supra.*
[124] *Id.*
[125] *Id.* at 3.
[126] *Id.* at 1.
[127] *Pain Assessment, supra*, at 4.
[128] *Id.*

insignificant addiction risk was false when made and remains false today. Yet it worked as intended to mislead treating doctors, medical staff, and patients into believing opioids could and should be utilized more often. Indeed, 74% of doctors "incorrectly believe morphine and oxycodone" are the "most effective ways to treat pain" even though research shows that over-the-counter pain relievers are the most effective for acute pain.[129] Even worse, 20% of doctors prescribing opioids prescribed at least a month's worth, even though the evidence shows that "30-day use causes brain changes."[130]

113. Patients also contributed to the pain epidemic by their reluctance to report their pain and to take medications,[131] according to *Pain Assessment.* Doctors were instructed to engage patients in conversations about their pain before prescribing opioids by: (1) asking for pain relief when the pain begins; (2) helping the doctor or nurse assess the pain; and (3) telling the doctor or nurse if the pain is not relieved.[132] Doctors were taught that "[t]he single most reliable indicator of the existence and intensity of pain is the individual's self-report."[133] Indeed, the individual's self-report was to be the ***primary*** source of information for the doctor and deemed more reliable than the observations of others.[134]

[129] National Safety Council, *supra.*
[130] *Id.*
[131] *Pain Assessment*, *supra*, at 4.
[132] *Pain Assessment*, *supra* at 8.
[133] *Id.* at 13.
[134] *Id.*

114. The bombardment of information, instruction, books, pamphlets, seminars, ads, and marketing regarding this "pain epidemic" was so successful that pain has been included as the "fifth vital sign" to be recorded along with the individual's temperature, pulse, respiration, and blood pressure.[135] This strategy was first pitched by the APS to ensure that pain management gained acceptance in the medical community, which it did.[136]

115. Beginning in 1999, the Veteran's Health Administration began routinely assessing pain as the fifth vital sign in every individual.[137] And according to *Pain Assessment*, the research showed that "when pain assessment information is included in clinical charts, those individuals' analgesics [meaning opioids] are more likely to be increased."[138] In other words, including pain as a fifth element results in not only the prescribing of more opioids, it results in the prescribing of higher doses of opioids.

116. *Pain Assessment* also framed the role of key opinion leaders ("KOL") as trustworthy people "to evaluate new clinical information, assess new practices, and then determine their value within the context of the local setting."[139] Doctors were expected to accept KOLs opinions even though KOLs are *not* "necessarily

[135] *Pain Assessment, supra*, at 20.
[136] *See id.* 20-21.
[137] *Id.* at 21.
[138] *Id.*
[139] *Pain Assessment, supra* at p. 24.

innovators or authority figures."[140] KOLs convinced practitioners that their current chronic pain treatment was "outdated, inappropriate, unsupported by research evidence, or no longer accepted by colleagues."[141]

117. Expert leaders, on the other hand, influenced and implemented protocols with individuals or small groups.[142] These "academic strategies" included "conducting interviews to determine baseline knowledge, stimulating active participation during educational sessions, using concise graphic educational materials, and highlighting or replicating essential messages."[143] Academic detailing was modeled after pharmaceutical detailing practices in which representatives visited physicians to talk about specific medicines, just as Defendants' representatives met with physicians to about opioids.[144] Simply put, *Pain Assessment* was a part of a marketing campaign to plow ground for Defendants to sell more opioids, and the book set forth sophisticated, multi-layered marketing strategies that were most effective in executing the campaign.

118. If a doctor was not available to prescribe opioids, a nurse would suffice. A nurse specializing in oncology, surgery, critical care, or a nurse anesthetist, as well as a clinical pharmacist, can "serv[e] as role models, provid[e] pain management

[140] *Id.*
[141] *Pain Assessment*, *supra* at 25.
[142] *Id.*
[143] *Pain Assessment*, *supra*, at 25.
[144] *See id.*

education and consultation, and act[s] as agents of change."[145] These educational efforts "significantly altered prescription practices."[146]

119. To succeed in prescribing opioids for chronic pain, Defendants had to create a market for chronic pain. To do so, Defendants literally encouraged patients not to tolerate pain and to fear pain *more* than opioid addiction.[147] Physicians and their staff were encouraged to educate their patients about "effective pain management," which included the use of opioids.[148] *Pain Assessment* explained research that showed Americans would rather bear pain because they were afraid of "addiction, dependence on drugs, and tolerance to medications," which affected not only the patient's willingness to report pain, but to use adequate amount of opioids to control the pain.[149] A patient's reluctance to take opioids out of fear they would not function normally meant that the problem was "underreported" and the pain went "untreated."[150]

120. Consequently, the answer was to inform and educate the patient that unrelieved pain is harmful and that he or she should communicate pain.[151] *Pain Assessment* instructed the use of pain assessment instruments, including pain intensity scales, to describe the nature of the pain and stressed that the "most reliable

[145] *Pain Assessment, supra.*
[146] *Id.*
[147] *Pain Assessment, supra* at 33.
[148] *Id.*
[149] *Id.*
[150] *Pain Assessment, supra*, at 33.
[151] *Pain Assessment, supra* at 35.

indicator of pain" was the individual's self-report.[152] Once the patient reported the pain, the physicians and staff were taught to tell the patient about opioids, explain that opioids were safe and effective, describe the name, dosage, and duration of the opioid therapy, and explain the risk of pain versus the importance of pain management.[153]

121. To ensure that patients self-reported pain prior to hospital visits, *Pain Assessment* encouraged health care systems to provide individuals and families with pain management information *prior* to being admitted.[154] And health care systems were told to leave individuals and family members with audio and videotapes to watch and listen to about the "importance" of "pain relief" so that they truly understood the message – that is, if you have "pain," tell us and we will provide opioids.

122. The JCAHO was not independent and did not improve the safety or quality of healthcare. Instead it was hijacked by Defendants to standardize pain management criteria that required the use of opioids for chronic pain. The JCAHO was merely a pawn in the Defendants' larger game.

[152] *Id.*
[153] *Pain Assessment*, *supra*..
[154] *Id.* at 36.

123. Like other books and pamphlets used by Defendants to spread their "message," *Pain Assessment* was distributed throughout the nation and in Montana. As of today, anyone can buy a used copy of *Pain Assessment* on Amazon.com.

b. Key Opinion Leaders (KOLs) were another Means of Disseminating False Information.

124. Defendants also sponsored KOLs, a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Defendants because they publicly supported dispensing opioids more widely and indiscriminately.

125. Defendants paid KOLs to serve as consultants or to appear on their advisory boards and to give talks or present CMEs, and Defendants' support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs promoted the benefits of opioids to treat chronic non-cancer pain, repaying Defendants by advancing their marketing goals.

126. KOLs wrote articles and books, gave speeches, and taught CMEs to promote the utilization of opioids to treat moderate non-cancer pain. Defendants created opportunities for KOLs to participate in "studies" and write papers for the purpose of advancing Defendants' marketing theme: opioids should be dispensed regularly and perpetually to treat a broad array of pain complaints.

127. Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage using opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select,

and present CMEs. Defendants were able to direct and exert control over each of these activities through their KOLs.

128. Pro-opioid doctors are one of the most important avenues that Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for using opioids for chronic pain.

129. Different Defendants utilized many of the same KOLs. Two of the most prominent are described below.

1. Russell Portenoy

130. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL who Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

131. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS")/American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in

2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by Defendants.

132. Dr. Portenoy also made frequent media appearances promoting opioids. He appeared on *Good Morning America* in 2010 to discuss using opioids long-term to treat chronic pain. On this widely-watched program, broadcast in Montana and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[155]

133. Perhaps realizing that "[m]ore than 16,000 people die from opioid overdoses every year," Dr. Portenoy is now having "second thoughts" about the "wider prescription" of drugs like Vicodin, OxyContin, and Percocet.[156] Dr. Portenoy later admitted in a 2010 videotaped interview that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[157] According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks.

[155] Good Morning America television broadcast, ABC News, Aug. 30, 2010.
[156] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J., Dec. 17, 2012, attached hereto as Exhibit D.
[157] Catan, *supra*.

134. Dr. Portenoy put doctors' fear that opioids were dangerous and addictive, and meant only for cancer patients, to rest by arguing that they could be taken safely for months, even years, by patients with chronic pain.[158] Dr. Portenoy, as well as other doctors making the speaker rounds, asserted that "[l]ess than 1% of opioid users became addicted, the drugs were easy to discontinue and overdoses were extremely rare in pain patients."[159]

135. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[160] Dr. Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well…I guess I did."[161]

136. Before his moment of clarity, Dr. Portenoy co-authored a guide to publicize the benefits of opioids for chronic pain, which was paid for by an unrestricted education grant from Endo, titled *A Clinical Guide to Opioid Analgesia* ("*Opioid Analgesia*").[162] *Opioid Analgesia* reiterated that opioids are "absolutely necessary" for pain relief.[163]

137. Although *Opioid Analgesia* claimed "to help clinicians make practical sense of the varied and often conflicting pharmacologic, clinical and regulatory

[158] Catan, *supra*.
[159] *Id.*
[160] *Id.*
[161] *Id.*
[162] Perry G. Fine, M.D. and Russell K. Portenoy, M.D., *A Clinical Guide to Opioid Analgesia*, McGraw-Hill, 2004.
[163] Fine, *supra* at 2.

issues to promote the most healthful outcomes possible for patients in pain,"[164] the reality was that it expressed regret that federal and state governments had passed controlled substances acts to stem addiction, which had curtailed the prescription of opioids.[165] This regulation, explained *Opioid Analgesia*, "contributed to the underuse of opioid medications."[166]

138. As with all other books, guidelines, and CMEs promoted by Front Groups and KOLs, *Opioid Analgesia* establishes the absolute need for opioids in light of the chronic pain epidemic. "Because pain is inherently subjective, patient self-report is the 'gold standard' for assessment."[167] If there's no discernible reason for the pain, then it should be characterized as "idiopathic."[168] Regardless of how the pain is characterized, the solution, per *Opioid Analgesia*, is opioids.

139. "While opioid analgesics are controlled substances, they are also essential medication and are absolutely necessary for relief of pain."[169] "Opioid analgesics should be accessible to all patients who need them for relief of pain."[170] Brushing away any concerns about addiction, *Opioid Analgesia* posits that "[a] patient who has reached middle age without developing compulsive use behaviors

[164] *Id.* at 3.
[165] Fine, *supra.*
[166] *Id.* at 6.
[167] Fine, *supra*, at 34.
[168] *Id.* at 35.
[169] *Id.* at Table 1.
[170] Fine, *supra.*

to potentially abusable drugs, including alcohol and nicotine, appears to be at a very low risk" of addiction, especially if "there is no family history of addiction."[171]

140. Underplaying the risks of addiction, *Opioid Analgesia* falsely claimed that "[o]verall, the literature provides evidence that the outcomes of the drug abuse and addiction are rare among patients who receive opioids for a short period (i.e., for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications."[172] Even while admitting there is "very little information about the risks of misuse, abuse, or addiction among different opioid-treated populations" and even admitting the "[w]hen misused, opioids pose a threat to society,"[173] Defendants' intentionally marketed opioids as effective and safe for treatment of chronic pain and summed up the risk of addiction for short-term therapy as "rare."[174]

141. Of course when addiction is as narrowly defined as it is in the books, CMEs, and guidelines that Defendants publishes, the risk of addiction would be termed as "rare." The behaviors cited in *Opioid Analgesia* as "probably more suggestive" of addiction included:

- Selling prescription drugs;
- Forging prescriptions;

[171] *Id.* at 21.
[172] *Id.*
[173] *Id.* at 31, 2.
[174] Fine, *supra*, at 34.

- Stealing or "borrowing" drugs from others;
- Injecting or inhaling (snorting, smoking) oral formulations; and
- Obtaining the prescription drugs from nonmedical sources.[175]

142. Whereas the following behaviors are "probably less suggestive" of addiction:

- Aggressive complaining about the need for more drug;
- Drug hoarding during periods of reduced symptoms;
- Requesting specific drugs; and
- Using the drug, without approval, to treat another symptom.[176]

143. Instead of these behaviors being symptoms of possible addiction, Dr. Portenoy terms these behaviors as a "phenomenon" termed "pseudoaddiction."[177] Pseudoaddiction allows physicians to discount these behaviors because "they are driven by desperation surrounding unrelieved pain" and are "eliminated by measures that relieve the pain, such as an increase in medication."[178] Instead of treating the "less suggestive" symptoms for what they are – signs of addiction.

144. *Opioid Analgesic* was a success for Defendants in that it has been and continues to be used extensively in CMEs, pamphlets, and reading lists for physicians looking for information regarding opioids. For example, *Opioid*

[175] Fine, *supra* at 85.
[176] *Id.*
[177] *Id.* at 35.
[178] Fine, *supra.*

Analgesia was recently cited in a presentation at the University of North Texas College of Pharmacy on April 28, 2017, entitled *Adverse Drug Events Associated with Opiate-Based Pain Management* (Emphasis Added). It has also been listed as a reference for a CME entitled *The Management of Opioid-Induced Constipation* published by the University of North Texas Health Science Center, which was valid for CME from May 2009 to May 2010. Finally, the book was included in the suggested reading list for a seminar entitled *When Opioids Are Indicated for Chronic Pain* presented on March 26, 2011, in Houston, Texas.

2. Lynn Webster

145. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise-unknown pain clinic in Salt Lake Cities, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports using opioids for chronic pain. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements recommending Opana ER. Dr. Webster authored numerous CMEs sponsored by Cephalon, Endo and Purdue while he was receiving significant funding from Defendants (including nearly $2 million from Cephalon).

146. In 2011, Dr. Webster presented a program via webinar sponsored by Purdue titled *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended using risk screening tools, such as urine testing and patient

agreements as a way to prevent "overuse of prescriptions" and "overdose deaths," which was available to and was intended to reach doctors treating residents in the Cities and Counties.

147. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to *increase* a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose "in most cases…should be the clinician's first response." Endo distributed this book to doctors.

148. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[179] Dr. Webster also admits that "[i]t's obviously crazy to think that only 1% of the population is at risk for opioid addiction."[180]

c. Front Groups Affirmed Defendants' Falsities.

149. Defendants entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for treating

[179] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, MILWAUKEE WISC. J. SENTINEL, Feb. 19, 2012.
[180] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J., Dec.17, 2012.

chronic pain. Under Defendants' direction and control, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored using opioids for chronic non-cancer pain. They also assisted Defendants by responding to negative articles, by advocating against regulatory changes that would limit prescribing opioids in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Defendants.

150. These Front Groups depended on Defendants for funding and, in some cases, for survival. Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Defendants made sure these Front Groups would generate only the messages Defendants wanted to distribute. Even so, the Front Groups held themselves out as independent and as serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

151. Defendants Cephalon, Endo, Janssen, and Purdue utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF") and Pain & Policy Studies Group ("PPSG").

1. American Pain Foundation ("APF")

152. APF was founded in 1997 and professed to be an independent non-profit 501(c)3 organization "serving people with pain through information, advocacy and support."[181] It had a membership of "close to 100,000 and growing" in 2010 and claimed to be the "largest advocacy group for people with pain."[182] The APF lauded its participation in "close to 100 policy activities," which included testifying at legislative hearings to securing state and local proclamations for Pain Awareness Month.[183]

153. APF, however, as the most prominent of Defendants' Front Groups, received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next at $1.7 million. Despite the influx of funds from pharmaceutical companies, APF claimed to be an independent patient advocacy group.

154. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009. In 2010, Endo paid APF more than $1 million and Purdue paid APF

[181] American Pain Foundation, *Treatment Options: A Guide for People Living with Pain*, www.painfoundation.org; *see also 2010 Annual Report*, American Pain Foundation.
[182] *2010 Annual Report*, *supra*.
[183] *Id.*

between $1 million and 4.9 million.[184] By 2011, APF was entirely dependent on incoming grants from Purdue, Cephalon, Endo, and others to avoid using its line of credit. One of its board members, Russell Portenoy, explained the lack of funding diversity was one of the biggest problems at APF.

155. APF issued education guides for patients, reporters, and policymakers that recommended opioids for chronic pain while trivializing their risks, particularly the risk of addiction. Its *Pain Community News*, an "esteemed" quarterly newsletter, had a print circulation of more than 68,000 plus additional online readers.[185] Its monthly electronic newsletter, *Pain Monitor*, was a monthly newsletter that provided links to pain-related news and research.[186] The APF also provided "patient representatives" for Defendants' promotional activities, including Purdue's *Partners Against Pain*[187] and Janssen's *Let's Talk Pain.*[188]

156. In one of its publications, *Treatment Options: A Guide for People Living with Pain*, ("*Treatment Options*"), APF recognized contributions from Cephalon and Purdue.[189] *Treatment Options* was reviewed by Scott Fishman, M.D., Vice Chairman of the APF Board of Directors, and Russell Portenoy, M.D., a Member of the APF

[184] *2010 Annual Report*, *supra.*
[185] *2010 Annual Report*, *supra* at 2.
[186] *2010 Annual Report*, *supra*, at 2.
[187] In its "Partner against Pain" website, Purdue claimed that the risk of addiction from the use of OxyContin in treating "chronic non-cancer pain" was "extremely small"; *see also* Zee, Ex. B, at 3.
[188] *Let's Talk Pain* was a "coalition effort that focus[ed] on supporting positive patient-provided communications" regarding pain.
[189] *Treatment Options*, *supra*, at ii.

Board of Directors and also a KOL.[190] *Treatment Options* set the stage for prescribing opioids by explaining their underuse despite their benefits.[191] It dismissed the risk of addiction with the rhetoric that physical dependence was nothing more than symptoms or signs of withdrawal that occurred when opioids were stopped suddenly or the dose lowered too quickly.[192]

157. *Responsible Opioid Prescribing* and *The War on Pain* both had a tremendous impact on doctors' prescribing habits. In 2000, Scott Fishman, M.D., who served on APF's board, co-authored *The War on Pain* ("*Pain War*") as general authoritative information about pain medicine."[193]

158. *Pain War* seeks new specialties in which opioids can be prescribed for chronic pain. Rheumatologists treating arthritis have been overlooked because they were more prone to prescribe NSAIDS instead of opioids, such as morphine.[194] But such "outdated ideas about addiction and concerns about social stigmas" need to evolve because opioids offer "substantial relief" with "less severe long-term side effects than chronic anti-inflammatories."[195]

159. *Pain War* advocates for physical dependence to opioids, and equates withdrawal symptoms from opioid drugs to that of cessation of coffee drinking. A

[190] *Id.* at iv.
[191] *Id.* at 11.
[192] *Id.* at 14 (referring to symptoms such as sweating, rapid heart rate, nausea, diarrhea, goosebumps, and anxiety).
[193] Scott Fishman, M.D., with Lisa Berger, *The War on Pain*, First Quill, 1st ed., 2000.
[194] *Id.* at 154.
[195] Fishman, *War on Pain*, *supra*, at *155.*

"pain patient who is dependent on opioids finds life restored," the book advises, and then explains that removing a patient from opioids causes physical, not psychological, consequences, like quitting *coffee*.[196] Addiction to opioids is treated as a "phobia" or "notion" that "using opioids" are "always addictive."[197]

160. *Pain War* censures the failure to prescribe opioids and even suggests that such failure is a criticism of the patient. For example:

> Doses tend to be too low, the right narcotic preparation tends to be avoided, and the prescribing period is often too short. Medicine's reluctance to use appropriate doses of opioid drugs gives patients the wrong message – their pain isn't that important, they are not trustworthy, they may be addicts, they are bad people if they take drugs even if they are prescribed.[198]

161. *Pain War* was distributed across the nation, and sold in Montana, as evidence by a third-party seller offering the used book for $15.99 plus $5.99 in shipping costs on Amazon.com.

162. As late as 2008, the APF was still relaying the same message. In *A Reporter's Guide: Covering Pain and Its Management* ("*Reporter's Guide*"), the APF extolled that "[t]he person with pain is the authority on the existence and severity of his/her pain. The self-report is [the] most reliable indicator."[199] The

[196] Fishman, *War on Pain*, *supra*, at 187.
[197] *Id.* at 185.
[198] *Id.*
[199] American Pain Foundation, *A Reporter's Guide: Covering Pain and Its Management*, Oct. 2008, at 1, attached hereto as Exhibit E.

Reporter's Guide referred to pain as a health crisis and concluded that it affected more Americans than "diabetes, heart disease and cancer combined."[200]

163. Yet APF, Defendants' Front Group also admitted that:

- 71% of people abusing prescription pain relievers received them from a friend or family member without a prescription;
- Approximately 2.2 million Americans abused pain medication for the first time in 2006; and
- Between 1992 and 2002, reported abuse by teenagers increased by 542%.[201]

164. Even though Defendants knew about the risks involved in prescribing opioids or ingesting opioids, they continued to disseminate a story about a "pain epidemic" that could be treated only through the use of opioids. Even a 542% increase in abuse by teenagers in the United States in the span of ten years did not make Defendants change their marketing strategy or otherwise modify their educational or promotional materials concerning the risks associated with the use of opioids.

165. In addition to these publications, APF also engaged in a significant multimedia campaign – through radio, television, and the internet – to educate patients about their "right" to pain treatment, namely opioids. APF's local and national media efforts resulted in 1,600 media stories on pain in 2010, which was an increase of 1,255% from 2009.[202] APF surmised that it reached more than 600

[200] *Reporter's Guide*, Ex. E at 29.
[201] *Reporter's Guide*, Ex. E, at 29.
[202] *Id.* at 15.

million people with information and education related to pain.[203] All of the programs and materials were available nationally and were intended to reach patients and consumers in the Cities and Counties.

166. APF's website was visited by nearly 275,000 people in 2010 and a National Pain Foundation was expected to be complete in 2011.[204] In May 2012, the U.S. Senate Finance Committee began investigating the financial ties between Front Groups and trade organizations, such as APF and the FSMB, and the opioid manufacturers. This investigation not only caused damage to APF's credibility but caused Defendants to cease its funding.

167. The Senate Finance Committee intended to investigate whether pharmaceutical companies were responsible for the opioid epidemic by "promoting misleading information about the drugs' safety and effectiveness."[205] The Senate Finance Committee was concerned that a "network of national organizations and researchers with financial connections to the makers of narcotic painkillers…helped create a body of dubious information 'favoring opioids' that can be found in prescribing guidelines, patient literature, position statements, books and doctor education courses."[206]

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[203] *Reporter's Guide*, Ex. E.
[204] *2010 Annual Budget*, *supra*, at 6
[205] *See* Letter to Dr. Humayun J. Chaudhy dated May 8, 2012 from Charles E. Grassley and Max Baucus, at p. 2.
[206] *Id. quoting* Milwaukee Journal Sentinel/MedPage Today, *Follow the Money: Pain, Policy, and Profit*, Feb. 19, 2012, *available at* at http://medpagetoday.com/Neurology/PainManagement/31256.

168. The Senate Finance Committee was especially concerned that "[a]mong the FSMB's educational initiatives has been the development and distribution of a guidebook intended to help physicians recognize the risk of opioids and follow responsible and safe prescribing standards."[207] (Emphasis in original.) Hence, Dr. Fishman and his book *Opioid Prescribing: A Physician's Guide*, the first edition of which was released in 2007 and later accredited by the University of Wisconsin School of Medicine and Public Health, was at the center of the investigation.[208]

169. The Senate Finance Committee asked for any grants or financial transfers used to produce the book, the revenue generated from the sale of the book, each state that distributed the book, and the names of any people or organization involved in writing or editing the book.[209]

170. Within days, APF's board voted to dissolve the organization and it ceased to exist. The FSMB responded to the Senate Finance Committee's inquiry, however, and agreed that "the abuse and misuse of opioids is a serious national problem."[210] Dr. Chaudhy, speaking on behalf of the FSMB, acknowledged that "prescription drug abuse and related deaths has grown at an alarming pace in the

[207] Chaudhy Letter, *supra*, at 5.
[208] *Id.*
[209] *Id.* at 3.
[210] Letter to Max Baucus and Charles Grassley dated June 8, 2012 from Humayun J. Chaudhy, DO, FACP, at 1.

United States."[211] Dr. Chaudhy described Dr. Fishman, the author of *Opioid Prescribing*, as "one of the nation's leading experts in pain medicine."[212]

171. *Opioid Prescribing* was released from 2007 through January 2012, was distributed in each of the 50 states, including Montana, and supported in the medical community as an educational resource for doctors.[213] The book is still being sold today on websites such as Amazon and Ebay. Dr. Fishman also toured and gave keynote speeches about *Opioid Prescribing*. The book was also used extensively by state regulators to make safe and responsible decisions about prescribing opioids.[214]

172. As described herein, Dr. Fishman and his book was partly funded by Endo, Purdue, and Abbott among others as evidenced in the response. In 2004, Purdue paid $87,895 in the form of a grant to the FSMB to update the FSMB *Model Guidelines for the Use of Controlled Substances in the Treatment of Pain*, along with other objectives related to opioids.[215] In 2005, Purdue paid $244,000 to FSMB and in 2006, Purdue paid $207,000 to FSMB for the continuation of the same project.[216] In 2008, Endo and Purdue each paid $100,000 in the form of a grant for the distribution of *Responsible Opioid Prescribing*.[217] Thus, from 2000-2012, Purdue paid $734,505.06 and Endo paid $411,620.00 to the FSMB and FSMB Foundation.

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[211] Chaudhy Letter, *supra*, at 1.
[212] Chaudhy, *supra* at 5.
[213] *Id.*
[214] Chaudhy, *supra*, at 5, 17.
[215] *Id.* at 11.
[216] *Id.* at 11-12.
[217] Chaudhy, *supra* at 12.

173. Dr. Chaudhy's response merely underscored Defendants' role, through KOLs and Front Groups, in controlling the message these groups conveyed about opioids.

2. American Academy of Pain Medicine ("AAPM")

174. The American Academy of Pain Medicine, with Defendants' assistance, prompting, involvement, and funding, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy.

175. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon, and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

176. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are…small and can be managed."[218]

177. Defendants influenced AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization. AAPM's staff understood they and their industry funders were engaged in a common task – propagate a "pain epidemic" and solve it by teaching that opioids were safe and effective for treating chronic pain.

178. In 1997, AAPM and the American Pain Society jointly issued a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed there was a low risk that patients

[218] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), *available at* http://www.medscape.org/viewarticle/500829.

would become addicted to opioids. The co-author of the statement, Dr. Haddox, was a paid speaker for Purdue at the time. Dr. Portenoy, Defendants' KOL, was the sole consultant. The consensus statement remained on AAPM's website until 2011.

179. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend using opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Endo, Cephalon, and Purdue.

180. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because he was concerned the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids. The Guidelines have been cited 732 times in academic literature, were disseminated in and around the

Cities and Counties during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

B. Defendants' Marketing Scheme Misrepresented the Risks and Benefits of Opioids.

181. To convince doctors and patients in the Cities and Counties that opioids can and should be used to treat chronic pain, Defendants had to convince them that long-term opioid use is non-addictive, safe, and effective. Knowing they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Defendants made claims that were not supported by, and were contrary to, the scientific evidence. Defendants have not corrected their misrepresentations.

182. Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risks of addiction and overdose, through a series of misrepresentations that have since been conclusively debunked by numerous published studies and the magnitude of human misery caused by Defendants' deceptions. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that opioids are the best treatment option for any recurrent moderate pain because: (1) only a miniscule number of patients, if any, would become addicted; (2) all patients with a substantial risk of becoming addicted to opioids could be readily identified; (3) patients who displayed signs of addiction probably were not addicted and, in any

event, could easily be weaned from the drugs; (4) the use of higher opioid doses do not escalate risk of addiction or overdose; and (5) "abuse-deterrent" opioids are reliably safe and effective for perpetual use. Defendants still espouse these misrepresentations today.

183. ***First,*** Defendants falsely claimed the risk of addiction is low and unlikely to develop when opioids are prescribed, as opposed to those obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids.[219] For example:

a) Actavis's predecessor caused a patient education brochure to be distributed in 2007 claiming opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond;

b) Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online;

c) Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.";

[219] *See, e.g.*, Manchikanti, Ex. A, at 22 (blaming adverse consequences on abuses and overuses instead of appropriately blaming opioids used as directed).

d) Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website, www.opana.com;

e) Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.";

f) Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated";

g) Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction [ ]." This publication is still available online; and

h) Detailers for Purdue, Endo, Cephalon, and Janssen in and around the Cities and Counties minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for opioid abuse with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

184. These claims contradict empirical evidence. As noted by the CDC, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])."[220] The CDC has explained that "[o]pioid pain medication use presents serious risks, including…opioid use disorder"

[220] Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016*, Mar. 18, 2016.

and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[221] In fact, as many as "1 in 4 patients receiving long-term opioid therapy in primary care settings struggle with opioid use disorder."[222] Among the 12 recommendations by the new CDC guidelines to improve patient care and safety is that non-opioid therapy is preferred for chronic pain unless there is active cancer or it is for palliative and end-of-life care.[223]

185. Defendants' long-standing claims that opioid addiction and overdose are anomalies largely attributable to patient abuse of the drug, are demonstrably false. Indeed, the majority of cases "involving injury and death occur in people using opioids *exactly* as prescribed…"[224]

186. In 2010, a study addressed the rates of opioid overdose with patients receiving average prescribed daily opioids versus patients receiving medically prescribed chronic opioid therapy.[225] The patients included those receiving three-plus opioid prescriptions within 90-days for chronic non-cancer pain between 1997 and 2005.[226] Patients who received 50-99 mg had a 3.7-fold increase in overdose risk (95% C.I. 1.5, 9.5) and a 0.7 annual overdose rate.[227]

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[221] *CDC Guideline, supra.*
[222] *Id.*
[223] *Id.*
[224] Manchikanti, Ex. A, at 22.
[225] Kate M. Dunn, Ph.D., Kathleen W. Saunders, J.D., *Overdose and Prescribed Opioids: Association among Chronic Non-Cancer Pain Patients*, Ann. Intern. Med., Dec. 10, 2010, at 2.
[226] Dunn, *supra.*
[227] *Id.*

187. The authors determined that even though opioids provide some pain relief for chronic pain, balancing the long-term risks with the benefits was still "poorly understood."[228] Those patients who had not received opioids lately had a lower risk of overdose, however, than patients consistently receiving opioids at a low dosage.[229]

188. The authors pointed to previous studies that indicated a rise in opioid-related overdoses with an increase in prescribing opioids for non-cancer pain, but the belief that such phenomenon was caused by patients obtaining opioids from non-medical sources.[230] This study proves for the first time, however, that the risk of overdose is directly linked to the prescription and use of medically prescribed opioids.[231]

189. The authors of a Washington study in which the authors obtained Washington Medicaid data from the Washington Heath Care Authority reached a similar conclusion.[232] The opioid prescription claim history was examined for each "opioid poisoning" for the months that enrollees received Medicaid FFS prescription benefits.[233] The authors concluded that a large percentage of opioid poisonings

[228] Dunn, *supra.*
[229] Dunn, *supra,* at 6.
[230] *Id.* at 7.
[231] *Id.*
[232] Deborah Fulton-Kehoe, Ph.D., *Opioid Poisonings in Washington State Medicaid: Trends, Dosing, and Guidelines*, 53 Medical Care 8, Aug. 2015, at 680.
[233] Fulton-Kehoe, *supra*..

happened at lower prescribed doses and in individuals who were not considered chronic users.[234]

190. The authors noted that previous opioid guidelines focused on opioid doses above 80-120 mg/d MED even though previous studies showed risk of opioid deaths and poisonings at much lower doses and that most non-methadone opioid poisonings had been prescribed below these guidelines levels.[235] The authors concluded that only a small percentage of patients are prescribed opioids at a dosage greater than 120 mg/d MED, but that a large percentage of the opioids poisonings have been occurring in patients taking lower doses and in patients not considered chronic users.[236] Overdoses were therefore occurring in patients prescribed opioids for chronic non-cancer pain at increased rates and the overdose risk increased with an average prescription dose.[237] The guidelines and other educational material regarding opioids need to be changed to reflect the opioid poisoning among this population.[238]

191. In fact, "[t]he majority of deaths (60%) occur in patients when they are given prescriptions based on prescribing guidelines by medical boards with 20% of deaths in low dose opioid therapy…"[239] The way to cure the "crisis of opioid use in

[234] Fulton-Kehoe, *supra*.
[235] *Id.* at 683.
[236] *Id.* at 684.
[237] *Id.*
[238] *Id.*
[239] Manchikanti, Ex. A, at 1.

the United States" is to change "inappropriate prescribing patterns, which are largely based on a lack of knowledge, perceived safety, and inaccurate belief of undertreatment of pain."[240]

192. Another study found that approximately 60% of overdoses occur in medical users of opioids prescribed by a single physician to manage chronic pain.[241] Non-medical users comprise only a statistical minority of opioid overdoses.[242]

193. Scientific evidence underscores the conclusion that low-dose opioid therapy for chronic pain, opioids taken as prescribed, opioids obtained from a single doctor, and opioids prescribed pursuant to prescribing guidelines cause many overdoses. Defendants, however, disseminated contrary messaging throughout their marketing campaigns to sell more opioids.

194. ***Second***, Defendants falsely instructed doctors and patients that signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudoaddiction" – a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue – and claimed that pseudoaddiction is substantiated by scientific evidence. For example:

a) Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as

[240] Manchikanti, Ex. A.
[241] Barbara Zedler, M.D., *Risk Factors for Serious Prescription Opioid-Related Toxicity or Overdose Among Veterans Health Administration Patients*, Pain Medicine, 2014, at 1912, attached hereto as Exhibit F.
[242] *Id.*

"requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. *Responsible Opioid Prescribing* remains for sale online. The 2012 edition continues to teach that pseudoaddiction is real;

b) Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction…refers to patient behaviors that may occur when pain is under-treated…. Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.";

c) Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials;

d) Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."; and

e) Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long- acting opioid.

195. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The CDC Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment…are unlikely to experience pain relief with longer-term use,"[243] and that physicians should "reassess[] pain and function within 1 month"[244] in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids"[245] because the patient is "not receiving a clear benefit."[246]

196. ***Third***, Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allowed them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients. Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting opioid therapy for chronic pain. For example:

a) Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's

[243] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*
[244] *Id.*
[245] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*
[246] *Id.*

speakers' bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts;

b) Purdue sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths;" and

c) As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

197. Once again, the 2016 CDC Guideline confirms these representations are false. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts – widely believed by doctors to detect and deter outcomes related to addiction and overdose.[247] As a result, the Guideline recognizes that doctors should not overestimate the risk screening tools for classifying patients as high or low risk for opioid addiction because they are insufficient to rule out the risks of long-term opioid therapy.[248]

[247] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*
[248] *Id.*

198. ***Fourth***, to underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem thereby failing to disclose the increased difficulty of stopping opioids after long-term use.

199. For example, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation."

200. Defendants deceptively minimized the significant symptoms of opioid withdrawal, which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use.

201. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be limited to "minimize the need to

taper opioids to prevent distressing or unpleasant withdrawal symptoms,"[249] because "*physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days.*"[250] (Emphasis Added.) The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence"[251] and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal"[252] and pausing and restarting tapers depending on the patient's response.

202. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."[253] Contrary to the *Treatment Options* distributed by the APF, withdrawal from opioids involves much more than mere "physical" dependence occurring only when opioids are stopped suddenly or the dose lowered too quickly.

203. ***Fifth***, Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical

[249] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*
[250] *Id.*
[251] *Id.*
[252] *Id.*
[253] *Id.*

to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. For example:

a) Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond;

b) Cephalon and Purdue sponsored *APF's Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online;

c) Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain.";

d) Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was available during the time period of this Complaint on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased….You won't 'run out' of pain relief.";

e) Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was

distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages;

f) Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will;

g) Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online;

h) Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages; and

i) Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose.

204. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established"[254] while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."[255]

[254] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*
[255] *Id.*

205. More specifically, the CDC explains, "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."[256] Similarly, there is an "increased risk for opioid use disorder, respiratory depression, and death at higher dosages."[257] That is why the CDC advises doctors to avoid increasing dosages above 90 morphine milligram equivalents per day.

206. ***Finally***, Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids reliably curb addiction and abuse.

207. More specifically, Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter use. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant in a way that suggested it was more difficult to misuse the product. This claim was false.

208. The FDA warned in a 2013 letter that there was no evidence Endo's design would provide a reduction in oral, intranasal or intravenous use.[258] Moreover, Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

[256] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra*.
[257] *Id.*
[258] *See FDA Statement: Original Opana ER Relisting Determination*, May 10, 2013.

209. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was designed to be or is crush-resistant. The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER.

210. Similarly, the 2016 CDC Guideline states that no studies support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,"[259] noting that the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[260]

211. These numerous, long-standing misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to underestimate those risks.

C. Defendants Grossly Overstated the Benefits of Chronic Opioid Therapy.

212. To convince doctors and patients that opioids should be used to treat chronic pain, Defendants had to persuade them that there was a significant benefit to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain."[261]

[259] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*
[260] *Id.*
[261] *Id.*

213. In fact, the CDC found no evidence showing "a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)"[262] and that other treatments were more or equally beneficial and less harmful than long-term opioid use.

214. Nonetheless, Defendants were legion in their misrepresentations that opioid drugs were appropriate for use as a long-term lifestyle. For example:

a) Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives;

b) Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects;

c) Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs;

d) Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function;

[262] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra*.

e) *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online;

f) Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in 2012;

g) Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website promoted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site;

h) Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast;

i) Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube;

j) Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health- related quality of life for chronic pain

patients." The Policymaker's Guide was originally published in 2011 and is still available online today; and

k) Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

215. These claims are unsupported by the scientific literature. The 2016 CDC Guideline explained, "There is no good evidence that opioids improve pain or function with long-term use"[263] and "complete relief of pain is unlikely."[264] The CDC reinforced this conclusion throughout its 2016 Guideline:

a) "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later….";[265]

b) "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.";[266] and

c) "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."[267]

216. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[268]

[263] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*
[264] *Id.* (emphasis added).
[265] *Id.*
[266] *Id.*
[267] *Id.*
[268] *Id.*

217. The 2016 CDC Guideline was not the first time a federal agency repudiated Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience…results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[269]

218. Defendants also falsely emphasized or exaggerated the risks of competing products like NSAIDs so that doctors and patients would look to opioids first for treating chronic pain. Once again, Defendants' misrepresentations contradicted non-industry sponsored scientific evidence. In addition, Purdue misleadingly promoted OxyContin as unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action.

219. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. The reason is that OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. Although the patient experiences a powerful

[269] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/ucm259240.htm.

initial response, there is little or no pain relief at the end of the dosing period because less medicine is released.

220. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a substantial number of chronic pain patients taking OxyContin experience it.

221. This "end of dose" failure not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

222. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue's sales representatives continue to tell doctors in and around the Cities and Counties that OxyContin lasts a full 12 hours.

D. Defendants also engaged in Other Unlawful, Unfair, and Fraudulent Misconduct.

223. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals.

224. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither are approved for or have been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients.

225. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should be used only for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

226. Despite this advisory, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

a) Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer, or non-cancer, related has limited

utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online;

b) Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain; and

c) In December 2011, Cephalon widely disseminated a journal supplement entitled "*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*" to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

227. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were safe and effective not only for treating chronic pain, but were also approved by the FDA for such uses.

228. Other Defendants herein participated in illicit and unlawful prescribing of its drugs. For example, Purdue did not report illegal prescribing of OxyContin until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets. In doing so, Purdue protected its own profits at the expense of public health and safety.

229. The State of New York also found that Endo failed to require sales representatives to report signs of addiction, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently

arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

E. Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations.

230. As part of their deceptive marketing scheme, Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S. and the Cities and Counties. For example, Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe opioids, but were less likely to be educated about treating pain and the risks and benefits of opioids.

231. Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them.

232. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors use

"additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients.

233. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

234. Defendants achieved their goal in targeting these vulnerable populations when the Arthritis Foundation published its *Guide to Pain Management* in 2003 ("*Pain Management Guide*").[270] The *Pain Management Guide* was published by a neutral third-party that not only believed the message Defendants had been selling for years, but it continued to relay that message to patients experiencing chronic pain – elderly patients with arthritis.[271]

235. The *Pain Management Guide* was intended for a population of "70 million Americans who have arthritis or other related diseases."[272] It parroted falsities, such as the low risk of developing an addiction to opioids and cited Defendants' false statistic: "The addiction rate from narcotics is approximately one percent."[273]

236. The Arthritis Foundation even accepted and repeated Defendants' distinction between dependence and addiction. A person with dependence suggests

[270] Susan Bernstein, *The Arthritis Foundation's Guide to Pain Management*, Arthritis Foundation, 2003.
[271] *Id.*
[272] *Id.*
[273] *Id.* at 70-71.

he or she would experience withdrawal symptoms upon stopping opioids while addiction "is a self-destructive, habitual use" of opioids.[274] The *Pain Management Guide* brushes aside concerns about addiction and recommends higher doses of opioids for patients who develop a dependence on opioids[275] – the exact message that Defendants had been spouting for years.

237. The fact that neutral third parties were relying on and buying Defendants' false propositions only verifies Defendants' successful fraud on the medical and non-medical community at large.

F. Although Defendants knew that their Marketing of Opioids was False and Deceptive, they Fraudulently Concealed their Misconduct.

238. Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew their misrepresentations were false and deceptive. Manufacturing Defendants and Distributor Defendants alike knew that the marketing scheme being promoted by Manufacturer Defendants was misleading, inaccurate, and simply false. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes.

[274] *Id.* at 70.
[275] Bernstein, *supra*.

239. In The Journal of the American Medical Association November 2002 edition, which Defendants meant to reach physicians throughout the nation, Purdue advertised OxyContin as a safe drug with minimal safety risks.[276] The ad depicts a man and boy fishing with a title in large white letters exclaiming that "THERE CAN BE LIFE WITH RELIEF" with "LIFE WITH RELIEF" as the largest words in the advertisement.[277] Purdue then informs physicians that "[t]he most serious risk associated with opioids, including OxyContin, is respiratory depression."[278]

240. Purdue fraudulently represented that respiratory depression was not only the most serious risk for its own drug OxyContin, but for opioids in general, even though it knew that opioids carried a risk of addiction and death.

241. The ad continues with benign side effects that may occur with the use of OxyContin, such as "constipation, nausea, sedation, dizziness, vomiting, pruritus, headache, dry mouth, sweating, and weakness."[279] These side effects are certainly a far cry from addiction or death. Of course this ad also claims that OxyContin is a "continuous around-the-clock analgesic," which is equally false.[280]

242. Because of the bold misrepresentations and omissions in its ads occurring in the October 2, 2002 JAMA issue, and one occurring in the November

[276] The Journal of American Medical Association, Nov. 13, 2002.
[277] JAMA, *supra* at 1, 3.
[278] *Id*.
[279] *Id*.
[280] JAMA, *supra*, at 1, 3.

13, 2002 issue, the FDA wrote a warning letter to Michael Friedman, the Executive Vice President and Chief Operating Officer of Purdue.[281] Mr. Abrams explained that "[y]our journal advertisements omit and minimize the serious safety risks associated with OxyContin, and promote it for uses beyond which have been proven safe and effective."[282] Mr. Abrams reprimanded Purdue for failing to present "any information" in the advertisement about the "potentially fatal risks" or the potential for abuse associated with OxyContin.[283]

243. Mr. Abrams was concerned that these advertisements suggested such a "broad use of [OxyContin] to treat pain without disclosing the potential for abuse with the drug and the serious, potentially fatal risks associated with its use. . . ."[284] Purdue's actions were "especially egregious and alarming" given "its potential impact on the public health."[285] Mr. Abrams pointed out to Purdue the reality that "[i]t is particularly disturbing that your November Ad would tout 'Life with Relief,' yet fail to warn that patients can die from taking OxyContin."[286]

244. Purdue Pharma has consistently disregarded serious harm that it knew OxyContin caused. For example, in Kentucky in 2001, three people and one estate sued Purdue for becoming addicted to OxyContin even though they were taking the

[281] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Michael Friedman, Exec. Vice Pres. and COO, Purdue Pharma L.P.
[282] Warning Letter, *supra* at 1.
[283] *Id.*
[284] *Id.* at 2.
[285] *Id.*
[286] *Id.* at 4.

drug as prescribed.[287] Several similar lawsuits were filed against Purdue by individuals.[288] Dr. J. David Haddox, an executive at Purdue, responded to these claims: "A lot of these people say, 'Well, I was taking the medicine like my doctor told me to,' and then they start taking more and more and more…I don't see where that's my problem."[289]

245. Not surprisingly, three current and former executives from Purdue plead guilty in 2007 to criminal charges that they misled regulators, doctors, and patients about OxyContin's risk of addiction.[290] In pleading guilty to misbranding charges, Purdue admitted it had fraudulently marketed OxyContin as a drug less prone to addiction and as having fewer side effects than other opioids.[291] In reality, unlike most other opioids, OxyContin contained pure oxycodone without any other ingredients, which made it a higher-dose narcotic despite its time-release design that Purdue hawked as ameliorating its addictive potential.[292]

246. Manufacturing Defendants avoided detection of their fraudulent conduct by disguising their role in the deceptive marketing through funding and using third parties, such as Front Groups and KOLs. Doctors and patients trusted

[287] Chris Kahn, *Maker of OxyContin Faces at least 13 Lawsuits,"* July 27, 2001, Port Arthur News.
[288] *Id.*
[289] Kahn, *supra.*
[290] *See* Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, May 10, 2007, *available at* http://www.nytimes.com/2007/05/10/business/11drug-web.html; *see also* Zee, Ex. B, at 3-4.
[291] *See* Meier, *supra.*
[292] *See id.*

these third parties and did not realize that it was the pharmaceutical companies that were actually feeding them false and misleading information.

247. Defendants also manipulated their promotional materials and the scientific literature to make it appear that the information promoted was accurate, truthful, and supported by objective evidence when it was not.

248. Thus, Defendants successfully concealed from the medical community and patients facts sufficient to arouse suspicion of the claims the Cities and Counties now assert. The Cities and Counties did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

G. By Increasing Opioid Prescriptions and Use, Defendants' Deceptive Marketing Scheme has fueled the Opioid Epidemic and Damaged the Communities in the Cities and Counties.

249. Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies reveal that many doctors and patients are unaware of or do not understand the risks or benefits of opioids. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more

than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.[293]

250. Defendants' deceptive marketing scheme caused, and continues to cause, doctors in and around the Cities and Counties to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' fraud, these doctors would not have prescribed as many opioids that negatively impacted residents of the Cities and Counties.

251. Defendants' deceptive marketing scheme also caused, and continues to cause, patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

252. Defendants' deceptive marketing has caused and continues to cause the prescription and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million.

[293] Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities*, Jan. 27, 2016, *available at* http://www.hazeldenbettyford.org/about-us/news-and-media/pressrelease/doctors-missing-questions-that-could-prevent-opioid-addiction.

253. The escalating number of opioid prescriptions written by doctors who were deceived by Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and the Cities and Counties. The increase in opioid prescriptions equals an increase in "disability, medical costs, subsequent surgery, and continued or late opioid use."[294]

254. Scientific evidence demonstrates a strong correlation between opioid prescriptions and addiction to opioids. In a 2016 report, the CDC explained that prescribing opioids has quadrupled since 1999, which has resulted in a parallel increase in opioid overdoses.[295] Indeed, there has been a two-third increase in overdose deaths from using opioids since 2000.[296] For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the cycle of opioid pain medication misuse that contributes to the opioid overdose epidemic."[297]

255. Due to the increase in opioid overdoses, first responders, such as police officers, have been and will continue to be in the position to assist people

[294] Manchikanti, Ex. A, at 23.
[295] CDC/NCHS, *National Vital Statistics System, Mortality*, CDC Wonder, Atlanta, GA: US Department of Health and Human Services, 2016, *available at* https://wonder.cdc.gov/; Rudd RA, Seth P, David F, Scholl L, *Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015*, Morb Mortal Wkly Rep., Dec. 16, 2016.
[296] CDC, *National Vital Statistics System, Mortality*, Morb Mortal Wkly Rep., Jan. 1, 2006, at 1378-82, Increases in Drug and Opioid Deaths – United States, 2000-2014.
[297] *CDC Guideline for Prescribing Opioids for Chronic Pain, supra; see also* Rudd, *supra*.

experiencing opioid-related overdoses.[298] In 2016, "over 1,200 law enforcement departments nationwide carried naloxone in an effort to prevent opioid-related deaths."[299]

256. Defendants' deceptive marketing scheme has also detrimentally impacted children in the Cities and Counties. Overprescribing opioids for chronic pain has made the drugs more accessible to school-aged children, who come into contact with opioids after they have been prescribed to friends or relatives in the same household.

257. Defendants' conduct has adversely affected Plaintiffs' child protection agencies in the number of children in foster care driven by parental drug addiction. Children with parents addicted to drugs tend to stay in foster care longer, and they often enter the system having experienced significant trauma, which makes these cases more expensive for cities and counties like the City of Great Falls, Anaconda-Deer Lodge County, Lake County, and City of Missoula.

258. Opioid addiction is one of the primary reasons that the Cities and Counties residents seek treatment for substance dependence. A significant number of admissions for drug addiction were associated with a primary diagnosis of opiate addiction or dependence.

[298] Tex. Att'y Gen. Op. No. KP-0168 (2017).
[299] *Id. citing* http://www.nchrc.org/law-enforcement/us-law-enforcement-who-carry-naloxone/.

259. But for Defendants' creation, through false and deceptive advertising and other unlawful and unfair conduct, of a virtually limitless opioid market, this opioid crisis would not have occurred, and the Cities and Counties would not have been harmed. Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids to which people are addicted come, directly or indirectly, through doctors' prescriptions.[300]

260. Law enforcement agencies have increasingly associated prescription drug addiction with violent and property crimes. Despite strict federal regulation of prescription drugs, local law enforcement agencies are faced with increasing diversion from legitimate sources for illicit purposes, including doctor shopping, forged prescriptions, falsified pharmacy records, and employees who steal from their place of employment. The opioid epidemic has prompted a growing trend of crimes against pharmacies including robbery and burglary. This ongoing diversion of prescription narcotics creates a lucrative marketplace.

261. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has also resulted in an explosion in heroin use. For example, heroin use has

[300] Nathaniel P. Katz, *Prescription Opioid Abuse: Challenges and Opportunities for Payers*, Am. J. Managed Care, Apr. 19 2013, at 5 ("The most common source of abused [opioids] is, directly or indirectly, by prescription."), *available at* http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n4/Prescription-Opioid-Abuse-Challenges-and-Opportunities-for-Payers.

more than doubled in the past decade among adults aged 18 to 25 years.[301] Moreover, heroin-related overdoses in the United States has more than quadrupled since 2010.[302]

262. The costs and consequences of opioid addiction are staggering. For example, in 2007, the cost of healthcare due to opioid addiction and dependence was estimated at 25 billion, the cost of criminal justice was estimated at 5.1 billion, and the cost of lost workplace productivity was estimated at 25.6 billion.

263. Prescription opioid addiction and overdose have an enormous impact on the health and safety of individuals, as well as communities at large, because the consequences of this epidemic reach far beyond the addicted individual.

264. The Cities and Counties have also expended funds for false claims submitted on the Cities and Counties health plans that were paid as medically necessary when they were not and prescriptions for opioids through worker's compensation benefits.

265. The repercussions for residents of the Cities and Counties therefore include job loss, loss of custody of children, physical and mental health problems, homelessness and incarceration, which results in instability in communities often already in economic crisis and contributes to increased demand on community

[301] Centers for Disease Control and Prevention, *Vital Signs: Today's Heroin Epidemic – More People at Risk, Multiple Drugs Abused*, MMWR 2015, *available at* https://www.cdc.gov/vitalsigns/heroin/index.html.
[302] *Id.*

services such as hospitals, courts, child services, treatment centers, and law enforcement. Manufacturing Defendants knew, and should have known, about the harms that their deceptive marketing has caused, and continues to cause, and will cause in the future. Manufacturing Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding.

266. Manufacturing Defendants also had access to and carefully watched government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. Manufacturing Defendants not only knew, but intended that their misrepresentations would persuade doctors to prescribe and encourage patients to use their opioids for chronic pain.

267. Manufacturing Defendants' actions are neither permitted nor excused by the fact that their drug labels may have allowed, or did not exclude, the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Manufacturing Defendants' misrepresentations were directly contrary to pronouncements by, and guidance from, the FDA based on the medical evidence and their own labels.

268. Nor is Manufacturing Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed decisions. And both doctors and patients in the Cities and Counties relied on information Manufacturing Defendants distributed whether it was through ads, magazines, trade journals, websites, CMEs, KOLs, and/or front groups. Manufacturing Defendants also hijacked what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

269. Likewise, Distributor Defendants knew when there was suspicious opioid prescription activity as they do today. They were in a unique position to forestall the epidemic in the Cities and Counties before it began. Instead, Distributor Defendants allowed a flood of opioids to be poured into the Cities and Counties. The Cities and Counties relied on Distributor Defendants to prevent oversupply with distribute prescription drugs, including opioids, only if a valid medical purpose existed. At the very least, the Cities and Counties depended on Distributor Defendants to act as watchful and effective gatekeepers in the opioid pipeline as they represent in their public statements. Distributor Defendants did neither to Plaintiffs' detriment, proximately causing damage to Plaintiffs.

270. The funds that the Cities and Counties have used and will continue to use for all the costs associated with Defendants' false, misleading, and fraudulent marketing are taxpayer funds. Defendants specifically targeted physicians in the Cities and Counties with fraudulent claims concerning the benefits of opioids for chronic pain while omitting the lack of efficacy.

271. Defendants also fraudulently omitted the fact that opioids were addictive even though they knew, or should have known, that physicians in the Cities and Counties would either use the misinformation Defendants relayed to them to prescribe opioids to the residents of the Cities and Counties, or give this information to the residents of the Cities and Counties, resulting in the over-prescribing and/or overuse of opioids in the Cities and Counties.

272. Defendants' actions and omissions were each a cause-in-fact of Plaintiffs' past and future damages. Defendants' wrongful conduct caused injuries to Plaintiffs in the past, continues to cause injuries to Plaintiffs, and will continue to cause injuries to Plaintiffs in the future. Future damages include, but are not limited to, additional resources for counseling and medication assisted treatment of addicts, medical treatment for overdoses, life skills training for adolescents, increased law enforcement, and additional resources to treat the psychological effects of opioids and the underlying conditions that make people susceptible to opioid addiction, all of which will be obtained through taxpayer resources.

H. Distributor Defendants Knew that Opioids were being Fraudulently Prescribed and Failed to Act.

273. Distributor Defendants are not innocent sellers of opioid drugs. Distributor Defendants knew that the marketing scheme promoted by Manufacturing Defendants was misleading, false, and deceptive. They knew that opioids were being industry promoted for the treatment of virtually any complaint of recurrent pain, and advertised as less addictive, less prone to abuse, less threatening for overdose, and more effective for perpetual use than was true. Nevertheless, they have deliberately shirked their duties to monitor suspiciously high prescription patterns, and have continued to feed the over-prescribing of opioid drugs. Distributor Defendants have long been aware of an opioid overuse epidemic in America, in Montana, and in the Cities and Counties, but chose in each instance to profit by stoking those epidemics with more opioids. Distributor Defendants knew that opioids were too often being prescribed without legitimate therapeutic purpose, but continued to inundate the market with opioids. Distributor Defendants were and continue to be an integral part of the opioid epidemic in the Cities and Counties.

274. As early as 2008, Distributor Defendants knew there was an opioid crisis and they were failing in their "critical role" in the supply chain to change or decrease the number of opioids being distributed into the market. McKesson paid a $13.25 million fine to settle claims regarding suspicious orders of opioids from

internet pharmacies in 2008.[303] Cardinal paid a $34 million fine for failing regarding suspicious distribution of hydrocodone in 2008.[304] Cardinal also had to close down its Lakeland, Florida warehouse because it turned a blind eye to the abundance of opioids funneling through only four pharmacies.[305] As such, McKesson and Cardinal knew by 2008, that their opioids were too often being oversupplied and distributed and, upon information and belief, that suspicion for diversionary purposes existed. This knowledge should have caused McKesson and Cardinal to better perform their duties to monitor non-therapeutic opioid prescription orders and to refrain from filling these orders as they occurred in the Cities and Counties. But instead McKesson and Cardinal doubled-down on profiting from an opioid epidemic, and did so in the Cities and Counties opioid epidemic.

275. No later than 2011, all Distributor Defendants knew there was a public health crisis throughout America created by opioid use. In 2011, the CDC announced that very thing.

276. Montana law specifically requires that dispensers like Distributor Defendants monitor opioid prescription orders and to refuse to fill prescription orders for opioids that are without valid medical purpose. In spite of the existence of an opioid epidemic in the Cities and Counties, and the fact that Distributor

[303] Eric Eyre, *"Suspicious" Drug Order Rules Never Enforced by State*, Charleston Gazette Mail, Dec. 18, 2016, *available at* www.wvgazettemail.com.
[304] *Id.*
[305] *See* Eyre, *supra*.

Defendants knew or should have known of that epidemic, Distributor Defendants continued to fill each opioid prescription order in the Cities and Counties, including those that were without valid medical purpose--thus stoking the epidemic.[306]

277. In 2017, Distributor Defendant McKesson publicly acknowledged its essential duty to monitor and to curb to therapeutic levels its distribution of opioid drugs. The chairman and chief executive officer of McKesson, John H. Hammergren, has said: "Pharmaceutical distributors play an important role in identifying and combatting prescription drug diversion and abuse…McKesson, as the nation's largest distributors, takes our role seriously."[307]

278. In an October 31, 2017 letter to Chris Christie, Chair of the President's Commission on Fighting the Drug and Opioid Crisis, Mr. Pete Slone, the Senior Vice President, Public Affairs, of McKesson admitted that the opioid crisis was the "public health crisis of our times" and was affecting communities at alarming rates.[308] Mr. Slone stated that both manufacturers and distributors should address the complicated opioid heath crisis.[309] Certainly, in public McKesson admits its responsibility and duty to the public with regard to distributing and disbursing

[306] CDC, *Prescription Painkiller Overdoses at Epidemic Levels*, Nov. 1, 2011, www.cdc.gov.
[307] Charles Ornstein, *Drug Distributors Penalized for Turning Blind Eye in Opioid Epidemic*, APR, Health News, Jan. 27, 2017; Letter from Pete Slone, Senior Vice President, Public Affairs, of McKesson, to The Honorable Chris Christie dated October 31, 2017.
[308] Pete Slone Letter, *supra*.
[309] *Id.*

opioids. It is only when McKesson is named in a lawsuit that it is suddenly blameless and has no responsibilities in stemming the tide of the opioid epidemic it helps fuel.

279. Amerisource agrees it has the same essential duty to monitor and to refrain from supplying suspicious opioid prescribing. On December 14, 2017, a press release announced that Amerisource, as a global healthcare solutions leader, "plays a critical role in the pharmaceutical supply chain, working as a link between manufacturers and healthcare providers to help patients have access to the medications they *need*, when they *need* them."[310] (Emphasis added).

280. Indeed, Amerisource's website is dedicated to its role as the "core strength" in U.S. drug distribution citing its "[t]remendous cash generation" and its "[d]iverse base of high quality provider customers."[311] Recognizing that the opioid epidemic could strike as many as 650,000 Americans over the next decade, Amerisource's CEO, Steve Collis, has assured the public that distributors like Amerisource are responsible for safely delivering medication to pharmacies given its "unique perspective into how [the] supply chain works."[312]

281. Mr. Collis agrees with people who are "rightfully demanding action on this tragic issue" and agrees to "push forward practical solutions that can yield results

[310] AmerisourceBergen Foundation, *AmerisourceBergen Foundation Launches Municipal Support Program to Help Combat Opioid Abuse*, Dec. 14, 2017 press release.
[311] Amerisource Bergen, *Distributor's Duty*, www.amerisourcebergen.com.
[312] Steven H. Collis, *Sound Policy and More Transparency can Help Companies Fight the Opioid Crisis*, Politics, Dec. 15, 2017.

in the near-term on opioids."[313] Remarking that it is "difficult to avoid the epidemic of opioid abuse," Mr. Collis adds that the opioid crisis is "demands attention, action, and accountability." [314] Mr. Collis explains that large pharmaceutical distribution companies, of which Amerisource is one, should be held accountable because "nearly every prescription in the United States moves through distributors who purchase drugs from pharmaceutical manufacturers and sell them to pharmacies…."[315] Mr. Collis explains that distributors like Amerisource "must create a supply chain that is safe and secure."[316] Mr. Collis even admits that as more opioid-based pain treatments were prescribed, more opioids were distributed.[317] The same views are expressed on Amerisource's website.[318]

282. On its website, Amerisource demonstrates that Distributor Defendants' ability to create a safe and secure supply chain is possible through "complex algorithms to identify and stop orders that are deemed to be suspicious."[319] Mr. Collis admits that Amerisource has "reported and stopped *tens of thousands* of suspicious orders since 2007, not to mention countless other orders that pharmacies

[313] *Id.*
[314] Steve Collis, *The Surprising Morality of Opioid Distribution*, Sept. 18, 2017, *available at* https://www.amerisourcebergen.com/abcnew/fighting-the-opioid-epidemic.
[315] *Id.*
[316] Collis, *supra.*
[317] *Id.*
[318] https://www.amerisourcebergen.com/abcnew/fighting-the-opioid-epidemic.
[319] *Id.*

never had the opportunity to place because [Amerisource] declined to service them altogether."[320] But not in the Cities and Counties.

283. Cardinal acknowledges on its website that the "opioid abuse crises dates back decades" and is due to "changes in prescribing patterns" for pain.[321] Like McKesson, Cardinal admits that the opioid epidemic is a "serious and complex" public health issue.[322]

284. Cardinal has been aware of this public health crisis for many years because it tracks and reports CDC opioid prescription and overdose death data. For example, Cardinal cites the fact that in 2015, 4.4 billion opioid prescriptions were filled, which equals about 12 prescriptions per person in the United States.[323] Out of these prescriptions, 11% were prescribed following surgery, injury, or for health conditions such as cancer.[324] Moreover, Cardinal recites that 1 in 4 patients using opioids long-term in a primary care situation struggle with opioid addiction.[325] Cardinal is also aware that in 2015, according to the CDC, there were more than 33,000 deaths that involved prescribed and non-prescribed opioids, and that opioid overdoses have quadrupled since 1999.[326] After tracking the opioid prescription data, Cardinal cannot now claim ignorance of the fact that many cities and counties in

[320] *Id.* (emphasis added).
[321] Cardinal Health, *No Demographic Group is Immune to this Crisis*, www.cardinalheatlh.com.
[322] *Id.*
[323] Cardinal Health, *No Demographic Group*, *supra*.
[324] *Id.*
[325] *Id.*
[326] *Id.*

Montana, including Plaintiffs, had an opioid prescription rate much higher than the National opioid prescription rate.

285. To deny such knowledge would be to deny Cardinal's role. Cardinal is part of a "multi-faceted and highly regulated healthcare system" in which "everyone in that chain, including [Cardinal] must do their part."[327] Cardinal believes it has a responsibility to provide a safe and secure channel to deliver medications, such as opioids.[328] This belief is underscored by Cardinal's Opioid Acton Program: Reclaiming Our Communities in which Cardinal states on its website that it operates a "state-of-the-art, constantly adaptive system to combat opioid diversion."[329] Cardinal claims it knows its pharmacy customers and uses a "multi-factor process to evaluate pharmacies" even before the pharmacies become Cardinal's customers.[330] To identify diversion and flag suspicious activity, Cardinal "engage[s] directly with pharmacists to understand their business, their purchasing patterns, the ration of controlled to non-controlled substances ordered and the demographics of their customers."[331] As a result, not only could Cardinal identify the suspicious ordering

[327] Cardinal Health, *Cardinal Health's Commitment to Opioid Anti-Diversion, Education and Misuse Prevention,* www.cardinalhealth.com.
[328] Cardinal Health, *No Demographic Group, supra.*
[329] Cardinal Health, *Opioid Action Program: Reclaiming our Communities,* www.cardinalhealth.com.
[330] *Id.* (making announced and unannounced site visits to pharmacies, which also includes hiring independent investigators specializing in pharmacy diversion and surveillance).
[331] *Id.*; Cardinal also uses an investigative team to perform on-the-ground investigations to determine whether heightened scrutiny is necessary. *Id.* For high-volume orders or orders that flag additional scrutiny, Cardinal has a senior committee of anti-diversion experts who recommend safeguards, which can include ending a business relationship with a customer or denying a business relationship with a new customer. *Id.*

patterns in the Cities and Counties, it had the power to stop the influx of opioids into the Cities and Counties.

286. Cardinal electronically monitors every order prior to fulfillment, especially controlled substances.[332] As a distributor, Cardinal has access to, and checks, the requisite information to see "whether the order deviates from historic ordering patterns in [Cardinal's] strict anti-diversion standards."[333] Suspicious orders are flagged for further "scrutiny and evaluation, including potentially canceling the order."[334]

287. Cardinal states on its website that it "refuse[s] to supply controlled substances to any pharmacy customer where [Cardinal] believe[s] there is an unreasonable risk of medication diversion."[335] This refusal is part of Cardinal's commitment to help solve the "complex national public health crisis."[336] Yet Cardinal continued to supply opioids to pharmacies in the Cities and Counties despite the data it reviewed.

288. Distributor Defendants knew their duty. Distributor Defendants had the means to carry out their duty and claim to have successfully done so at times in the past. Distributor Defendants acknowledge that their duty is ongoing. With regards

[332] *Id.*
[333] *Id.*
[334] *Id.*
[335] Cardinal Health, *Cardinal Health's Commitment, supra.*
[336] *Id.*

to opioids, however, Distributor Defendants continuously evade their gatekeeping duties, including but not limited to, in the Cities and Counties.

289. According to *The Charleston Gazette-Mail*, Distributor Defendants shipped nearly 9 million hydrocodone pills over two years to one pharmacy in the town of Kermit, West Virginia.[337] Kermit, West Virginia has a population of 392. Drug wholesalers distributed 780 million pills of oxycodone and hydrocodone in the state over six years. According to the *Gazette*, "[t]he unfettered shipments amount to 433 pain pills for every man, woman and child in West Virginia."[338]

290. Refusing to take action or turning a blind eye to suspicious spikes in opioid prescriptions has for the Distributor Defendants simply become a pesky cost of doing business. McKesson and Cardinal did not take sufficient heed of the multi-million dollar fines each had paid in 2008. McKesson agreed to pay a $150 million fine on January 17, 2017. Cardinal Health reached a $44 million settlement in December 2016; Cardinal also agreed in January 2017 to pay $20 million to the state of West Virginia; and Amerisource agreed to pay $16 million to the state of West Virginia.[339]

291. According to a 60 Minutes/Washington Post joint investigation, "[t]he pharmaceutical industry is doing everything it can to keep [the opioid] epidemic

[337] Charles Ornstein, *Drug Distributors Penalized for Turning Blind Eye in Opioid Epidemic*, APR, Health News, Jan. 27, 2017.
[338] Ornstein, *supra*.
[339] Ornstein, *supra*.

going."[340] McKesson certainly did not recognize any sort of "due diligence" while it was providing "millions and millions and millions of pills to countless pharmacies through the United States."[341] Since the 1990s, McKesson has made billions from distributing addictive opioids.[342] McKesson has admitted that when it came to the opioid crisis and pills flooding American communities, there was plenty of blame to go around, including drug makers, other distributors, doctors, and pharmacies.[343]

292. If McKesson had used their authority in the supply chain, the opioid epidemic would not be "nowhere near" where it is today.[344] In McKesson's role as a distributor, not a day went by that something suspicious was not happening, but McKesson never reported any suspicious activity, according to the 60 Minutes investigation.[345] McKesson "fueled the explosive prescription drug abuse problem in this country."[346]

293. McKesson repeatedly filled suspicious orders of the most commonly abused and prescribed opioid drugs oxycodone and hydrocodone.[347] McKesson, as did other Distributor Defendants, failed in their duty to act.

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[340] 60 Minutes, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country's Largest Drug Distributor,* CBS News, Dec. 17, 2017.
[341] *Id.*
[342] *Id.*
[343] *Id.*
[344] 60 Minutes, *supra.*
[345] 60 Minutes, *supra.*
[346] Too Big to Prosecute, *supra*.
[347] *Id.*

294. Distributor Defendants were in a unique position to see the results of Manufacturing Defendants' fraudulent marketing scheme. Distributor Defendants knew or should have known that there was a sharp increase in the prescription and distribution of opioids. Distributor Defendants undertook the responsibility to prevent opioids from being dispensed or disbursed for diversionary purposes − with a multi-faceted system to monitor and prevent they developed long ago, *according to their own published public proclamations* – and breached that duty Like Manufacturing Defendants, Distributor Defendants chose profits over duty, in breach of duty.

I. FACTS PERTAINING TO CLAIMS UNDER RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ("RICO") ACT

a. The Opioid Marketing Enterprise

1. The Common Purpose and Scheme of the Opioid Marketing Enterprise

295. Knowing their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-cancerous pain, the RICO Marketing Defendants[348] formed an association-in-fact enterprise and schemed to unlawfully increase their profits and sales, and grow their share of the prescription painkiller

[348] The RICO Marketing Defendants referred to in this section are those named in the Sixth and Seventh Claims for Relief under 28 U.S.C. § 1964(c), including Purdue, Cephalon, Janssen, and Endo.

market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain.

296. In order to unlawfully increase the demand for opioids, the RICO Marketing Defendants formed an association-in-fact enterprise (the "Opioid Marketing Enterprise") with the "Front Groups" and KOLs described above. Through their personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose. The RICO Marketing Defendants' substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

297. The RICO Marketing Defendants, through the Opioid Marketing Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including Plaintiffs, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing present no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative

forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

298. The scheme devised, implemented and conducted by the RICO Marketing Defendants was a common course of conduct designed to ensure that the RICO Marketing Defendants unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the RICO Marketing Defendants' drugs. The RICO Marketing Defendants, the Front Groups, and the KOLs acted together for a common purpose and perpetuated the Opioid Marketing Enterprise's scheme, which included the unbranded promotion and marketing network as described above.

299. The RICO Marketing Defendants, Front Groups and KOLs communicated regularly and shared information, coordinated misrepresentations, and exchanged payments. The RICO Marketing Defendants, Front Groups, and KOLs continue to share information about overcoming objections and resistance to opioid use for chronic pain through the coordination, communication and payment, which has occurred, and continues to occur, through the repeated and continuing use of the wires and mail. At all times, the RICO Marketing Defendants, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the

Opioid Marketing Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

300. At all relevant times, the Front Groups knew of the RICO Marketing Defendants' conduct, willingly participated, and benefited from their conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Cities and Counties. But for the Opioid Marketing Enterprise's unlawful fraud, the Front Groups had no incentive to disclose the RICO Marketing Defendants' and the Opioid Marketing Enterprise's deceit to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose while reaping substantial benefits.

301. At all relevant times, the KOLs were aware of, willing participants in, and benefitted from the RICO Marketing Defendants' conduct. The RICO Marketing Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The RICO Marketing Defendants' support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the RICO Marketing Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLS and Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and

Plaintiffs. But for the Opioid Marketing Enterprise's unlawful conduct, the KOLs would not have hid the RICO Marketing Defendants' and the Opioid Marketing Enterprise's deceit. By failing to disclose this information, KOLs furthered the Opioid Marketing Enterprise's scheme and common purpose while reaping substantial benefits.

302. The RICO Marketing Defendants, Front Groups and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Marketing Enterprise. As described herein, the Opioid Marketing Enterprise's conduct in furtherance of the common purpose of the Opioid Marketing Enterprise involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain (described in detail above); (2) lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or undermine CDC guidelines; (4) efforts to limit prescriber accountability; and (5) Defendants' lobbying is not itself alleged to be unlawful, but is further evidence of Defendants' state of mind in furtherance of unlawful activities.

303. In addition to disseminating misrepresentations about the risks and benefits of opioids, the Opioid Marketing Enterprise also furthered its common purpose by criticizing or undermining CDC Guideline. Members of the Opioid Marketing Enterprise criticized or undermined the CDC Guideline, which

represented an important step in limiting the amount of opioids prescribed for chronic pain.

304. In 2015, for example, several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized the CDC draft guidelines by insinuating lack of transparency because the guidelines did not disclose the names, affiliation, and conflicts of interest of the individuals who constructed the guidelines.

305. In 2016, the AAPM criticized the guidelines through its immediate past president, who argued that the CDC guideline was too strong and disproportionate to the small select portion of the available clinical evidence used to construct the guidelines.

306. The RICO Marketing Defendants needed the Front Groups and KOLs, who were perceived as "neutral" and more "scientific" than the RICO Marketing Defendants themselves, to accomplish the Opioid Marketing Enterprise's mission. Without the Front Groups and KOLs spreading misrepresentations about opioids, the Opioid Marketing Enterprise could not have achieved its common purpose.

307. The impact of the Opioid Marketing Enterprise's scheme is still in place − *i.e.*, opioids continue to be prescribed and used for even moderate chronic pain throughout the Cities and Counties and the opioid epidemic continues to injure the Cities and Counties, and consume health care and law enforcement resources.

308. Clearly, the RICO Marketing Defendants, the Front Groups, and the KOLs were each willing participants in the Opioid Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

2. The Conduct of the Opioid Marketing Enterprise Violated Civil RICO

309. From approximately the late 1990s to the present, each of the RICO Marketing Defendants exerted control over the Opioid Marketing Enterprise and participated in the operation or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a) Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was more likely to be relied upon by physicians, patients, and payors;

b) Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was more likely to be relied upon by physicians, patients, and payors;

c) Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was more likely to be relied upon by physicians, patients, and payors;

d) Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was more likely to be relied upon by physicians, patients, and payors;

e) Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;

f) Providing substantial opportunities for KOLs to participate in research studies on topics the RICO Marketing Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

g) Paying KOLs to serve as consultants or on the RICO Marketing Defendants' advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically over meals or at conferences;

h) Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;

i) Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the RICO Marketing Defendants suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

j) Paying significant amounts of money to the leaders and individuals associated with Front Groups;

k) Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;

l) Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

m) Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

n) Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;

o) Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the RICO Marketing Defendants, such as veterans and the elderly, and then funding that distribution;

p) Concealing their relationship to and control of Front Groups and KOLs from the Cities and Counties and the public at large; and

q) Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

310. The Front Groups also conducted and participated in the conduct of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a) The Front Groups promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the RICO Marketing Defendants' messages;

b) The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials claiming that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c) The Front Groups echoed and amplified messages favorable to increased opioid use − and ultimately, the financial interests of the RICO Marketing Defendants;

d) The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e) The Front Groups strongly criticized the 2016 guidelines from the CDC when it recommended limits on opioid prescriptions for chronic pain; and

f) The Front Groups concealed their connections to the KOLs and the RICO Marketing Defendants.

311. The RICO Marketing Defendants' Front Groups have had a tremendous impact on policymakers and the public. The larger Front Groups "likely have a substantial effect on policies relevant to their industry sponsors."[349] "By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."[350]

312. The KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a) The KOLs promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the RICO Marketing Defendants' messages themselves;

[349] *Fueling an Epidemic*, *supra* note 85, at 1.
[350] *Fueling an Epidemic*, *supra* at 2.

b) The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c) The KOLs echoed and amplified messages favorable to increased opioid use − and ultimately, the financial interests of the RICO Marketing Defendants;

d) The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e) The KOLs strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f) The KOLs concealed their connections to the Front Groups and the RICO Marketing Defendants, and their sponsorship by the RICO Marketing Defendants.

313. The scheme devised and implemented by the RICO Marketing Defendants and members of the Opioid Marketing Enterprise, amounted to a common course of conduct intended to increase the RICO Marketing Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

3. The RICO Marketing Defendants Controlled and Paid Front Groups and KOLs to Promote and Maximize Opioid Use

314. As discussed in detail above, the RICO Marketing Defendants funded and controlled the various Front Groups, including APF, AAPM/APS,

FSMB, Alliance for Patient Access, USPF, and AGS. The Front Groups, which only appeared to be independent, transmitted the RICO Marketing Defendants' misrepresentations. The RICO Marketing Defendants and the Front Groups thus worked together to promote the goals of the Opioid Marketing Enterprise.

315. Similarly, as discussed in detail above, the RICO Marketing Defendants paid KOLs, including Drs. Portenoy, Fine, Fishman, and Webster, to spread their misrepresentations and promote their products. The RICO Marketing Defendants and the KOLs thus worked together to promote the goals of the Opioid Marketing Enterprise.

4. Pattern of Racketeering Activity

316. The RICO Marketing Defendants' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of racketeering activity as described herein.

317. The pattern of racketeering activity used by the RICO Marketing Defendants and the Opioid Marketing Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain. The RICO Marketing Defendants' goal was to

increase sales and profits by inducing consumers, prescribers, regulators, and the Cities and Counties to rely on the RICO Marketing Defendants' misrepresentations.

318. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which the RICO Marketing Defendants, the Front Groups and the KOLs defrauded and intended to defraud Montana consumers, the Cities, the Counties, and other intended victims.

319. The RICO Marketing Defendants devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute and non-cancer pain. The RICO Marketing Defendants and members of the Opioid Marketing Enterprise knew that these representations violated the FDA approved use of these drugs, and were not supported by actual evidence. The RICO Marketing Defendants intended that that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance, and for the purpose of executing, their illegal scheme.

320. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain to prescribers,

regulators and the public, including Plaintiffs, the RICO Marketing Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

321. The RICO Marketing Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, *inter alia*:

a) Marketing materials about opioids, and their risks and benefits, which the RICO Marketing Defendants sent to health care providers, transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country, including the Cities and Counties;

b) Written representations and telephone calls between the RICO Marketing Defendants and Front Groups regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

c) Written representations and telephone calls between the RICO Marketing Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

d) E-mails, telephone and written communications between the RICO Marketing Defendants and the Front Groups agreeing to or implementing the opioids marketing scheme;

e) E-mails, telephone and written communications between the RICO Marketing Defendants and the KOLs agreeing to or implementing the opioids marketing scheme;

f) Communications between the RICO Marketing Defendants, Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

g) Communications between the RICO Marketing Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

h) Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout the Cities and Counties that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and

i) Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.

322. In addition to the above-referenced predicate acts, it was intended by and foreseeable to the RICO Marketing Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks.

323. The RICO Marketing Defendants, and each member of the Opioid Marketing Enterprise agreed, with knowledge and intent, to the overall objective of the RICO Marketing Defendants' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

324. Indeed, for the RICO Marketing Defendants' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the RICO Marketing Defendants each financed, supported, and worked through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines.

325. The RICO Marketing Defendants' predicate acts all had the purpose of creating the opioid epidemic that substantially injured the Cities and Counties, while simultaneously generating billion-dollar revenue and profits for the RICO Marketing Defendants. The predicate acts were committed or caused to be committed by the RICO Marketing Defendants through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

B. The Opioid Supply Chain Enterprise

326. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to "a categorical denial of any criminal behavior or intent."[351] Defendants' actions went far beyond what could be considered ordinary business conduct. For more than a decade, certain Defendants, the "RICO Supply Chain Defendants" (Purdue,

[351] McKesson Responds to Recent 60 Minutes Story About January 2017 Settlement With the Federal Government, McKesson,http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response

Cephalon, Endo, Actavis, McKesson, Cardinal, and AmerisourceBergen)[352] worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

327. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, Congress enacted the Controlled Substances Act ("CSA"). Specifically, through the CSA, Congress established a closed system of distribution for controlled substances. CSA imposes a reporting duty that cuts across company lines. Regulations adopted under the CSA require that companies, who are entrusted with permission to operate within this system, cannot simply operate as competitive in an "anything goes" profit-maximizing market. Instead, the statute tasks them to watch over each other with a careful eye for suspicious activity. Driven by greed, Defendants betrayed that trust and subverted the constraints of the CSA's closed system to conduct their own profit-driven enterprise.

[352] The RICO Supply Chain Defendants referred to in this section are those named in the Sixth and Seventh Claims for Relief under 28 U.S.C. § 1964(c), including Manufacturing Defendants Purdue, Cephalon, Janssen, Endo, Actavis, and Distributing Defendants McKesson, Cardinal and AmerisourceBergen.

328. As "registrants" under the CSA, the RICO Supply Chain Defendants are duty bound to identify and report "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[353] Critically, these Defendants' responsibilities do not end with the products they manufacture or distribute − there is no such limitation in the law because their duties cut across company lines. Thus, when these Defendants obtain information about the sales and distribution of other companies' opioid products, as they did through data mining companies like IMS Health, they were legally obligated to report that activity to the DEA.

329. The RICO Supply Chain Defendants' scheme required the participation of all. If any one member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the DEA to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare Distribution Alliance ("HDA"), the RICO Supply Chain Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of

[353] 21 C.F.R. § 1301.74(b).

Controlled Substances." Privately, the RICO Supply Chain Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied.

330. As described above, at all relevant times, the RICO Supply Chain Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute. In support of this common purpose and fraudulent scheme, the RICO Supply Chain Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

331. At all relevant times, as described above, the RICO Supply Chain Defendants exerted control over, conducted and/or participated in the Opioid Supply Chain Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids

in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:

332. The RICO Supply Chain Defendants disseminated false and misleading statements to state and federal regulators claiming that:

a) The quotas for prescription opioids should be increased;

b) They were complying with their obligations to maintain effective controls against diversion of their prescription opioids;

c) They were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;

d) They were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and

e) They did not have the capability to identify suspicious orders of controlled substances.

333. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[354]

[354] *HDMA is Now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution- alliance/ (last updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-

334. The CSA and the Code of Federal Regulations require the RICO Supply Chain Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations is a criminal violation of the statute.

335. The RICO Supply Chain Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Marketing Defendants' applications for production quotas. Specifically, the RICO Supply Chain Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

336. The RICO Supply Chain Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and

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dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13d7c704ef9fd9story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcementslowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail (Feb. 18, 2017), http://www.wvgazettemail.com/news/20170218/dea-agent-we- had-no-leadership-in-wv-amid-flood-of-pain-pills.

material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

337. In devising and executing the illegal scheme, the RICO Supply Chain Defendants devised and knowingly carried out a material scheme and/or artifice to defraud through materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

338. For the purpose of executing the illegal scheme, the RICO Supply Chain Defendants committed racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme. These racketeering acts, which included repeated acts of mail fraud and wire fraud, constituted a pattern of racketeering.

339. The RICO Supply Chain Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Marketing Defendants, the Distributor Defendants, or third parties that were foreseeably caused to be sent as a result of the RICO Supply Chain Defendants' illegal scheme, including but not limited to:

a) The prescription opioids themselves;

b) Documents and communications that supported and/or facilitated the RICO Supply Chain Defendants' request for

higher aggregate production quotas, individual production quotas, and procurement quotas;

c) Documents and communications that facilitated the manufacture, purchase and sale of prescription opioids;

d) RICO Supply Chain Defendants' DEA registrations;

e) Documents and communications that supported and/or facilitated RICO Supply Chain Defendants' DEA registrations;

f) RICO Supply Chain Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

g) Documents and communications related to the RICO Supply Chain Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h) Documents intended to facilitate the manufacture and distribution of the RICO Supply Chain Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i) Documents for processing and receiving payment for prescription opioids;

j) Payments from the Distributors to the Marketing Defendants;

k) Rebates and chargebacks from the Marketing Defendants to the Distributors Defendants;

l) Payments to the RICO Supply Chain Defendants' lobbyists through the PCF;

m) Payments to the RICO Supply Chain Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n) Deposits of proceeds from the RICO Supply Chain Defendants' manufacture and distribution of prescription opioids; and

o) Other documents and things, including electronic communications.

340. The RICO Supply Chain Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

Defendant Group Name	Company Names	Drugs		
		Drug Name	**Chemical Name**	**CSA Schedule**
Purdue	(1) Purdue Pharma L.P.; (2) Purdue Pharma Inc.; (3) The Purdue Frederick Company.	OxyContin	Oxycodone Hydrocodone extended release	Schedule II
		MS Contin	Morphine sulfate extended release	Schedule II
		Dilaudid	Hydromorphone hydrochloride	Schedule II
		Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
		Butrans	Buprenorphine	Schedule II
		Hysinga ER	Hydrocodone bitrate	Schedule II
		Targiniq ER	Oxycodone hydrochloride	Schedule II
	(1) Cephalon, Inc.;	Actiq	Fentanyl citrate	Schedule II

Cephalon	(2) Teva Pharmaceutical Industries, Ltd.;	Fentora	Fentanyl citrate	Schedule II
	(3) Teva Pharmaceuticals USA, Inc.	Generic Oxycodone	Oxycodone hydrochloride	Schedule II
Endo	(1) Endo Health Solutions, Inc.; (2) Endo Pharmaceuticals, Inc.; (3) Qualitest Pharmaceuticals, Inc. (*a wholly-owned subsidiary of Endo)*	Opana ER	Oxymorphone hydrochloride extended release	Schedule II
		Opana	Oxymorphone hydrochloride	Schedule II
		Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
		Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
		Generic	Oxycodone	Schedule II
		Generic	Oxymorphone	Schedule II
		Generic	Hydromorphone	Schedule II
		Generic	Hydrocodone	Schedule II
Allergan	(1) Allergan Plc; (2) Actavis LLC; (3) Actavis Pharma, Inc.; (4) Actavis Plc; (5) Actavis, Inc.; (6) Watson Pharmaceuticals, Inc.;	Kadian	Morphine Sulfate	Schedule II
		Norco (generic Kadian)	Hydrocodone and acetaminophen	Schedule II
		Generic Duragesic	Fentanyl	Schedule II
		Generic Opana	Oxymorphone hydrochloride	Schedule II

	(7) Watson Pharma, Inc.			

341. Each of the RICO Supply Chain Defendants identified manufactured, shipped, paid for and received payment for the drugs identified above, throughout the United States and in the Cities and Counties.

342. The RICO Supply Chain Defendants used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Supply Chain Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

343. At the same time, the RICO Supply Chain Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

344. The RICO Supply Chain Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

345. The RICO Supply Chain Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme. The main and wire transmissions described herein were made in furtherance of the RICO Supply Chain Defendants' scheme and common course of conduct to deceive regulators, the public, and the Cities and Counties that these Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Supply Chain Defendants' scheme and common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

346. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous opioids. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

347. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were

committed, or caused to be committed, by Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

348. The RICO Supply Chain Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against the RICO Supply Chain Defendants supports the conclusion that the RICO Supply Chain Defendants engaged in a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.

349. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, Plaintiffs' communities and Plaintiffs. The RICO Supply Chain Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or Plaintiffs. The RICO Supply Chain Defendants were aware that Plaintiffs and their citizens rely on these Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

350. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the RICO Supply Chain Defendants engaged in a fraudulent

scheme and unlawful course of conduct constituting a pattern of racketeering activity.

J. THE PHARMACY DEFENDANT'S UNLAWFUL DISTRIBUTION OF, FAILURE TO MONITOR, AND REFUSING TO FILL OPIOID PRESCRIPTIONS

351. Pharmacy Defendant CVS owes a duty under both federal law (21 U.S.C. § 823, 21 CFR 1301.74) and Montana Law (e.g., MT Food, Drug & Cosmetic Act), to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Plaintiffs' communities, as well as those which CVS knew, or should have known, were likely to be diverted into the Cities and Counties.

352. Pharmacy Defendant CVS similarly had industry-specific knowledge of the particular risks and harms from filling prescriptions for non-medical purposes and the resulting widespread opioid abuse.

353. Pharmacy Defendant CVS, through their words or actions set forth in news reports and other public documents, has acknowledged these risks and assured the public that issues affecting public health and safety are their highest priority.

354. In 2015, CVS publicly stated that, "the abuse of controlled substance pain medication is a nationwide epidemic that is exacting a devastating toll upon individuals, families and communities. Pharmacists have a legal obligation under State and Federal law to determine whether a controlled substance was issued for a

legitimate purpose and to decline to fill prescriptions they have reason to believe were issued for a non-legitimate purpose."

355. Despite knowing and even warning of these risks, Pharmacy Defendant CVS recklessly or negligently permitted diversion to occur. In failing to take adequate measures to prevent substantial opioid-related injuries to the nation, Pharmacy Defendant CVS has breached its duties under the "reasonable care" standard of Montana common law (including violating a voluntarily-undertaken duty to the public which they have assumed by their own words and actions), professional duties under the relevant standards of professional practice, and requirements established by Montana and Federal laws and regulations.

356. Pharmacy Defendant CVS was on notice of their ongoing negligence or reckless misconduct towards the nation, in part because of their history of being penalized for violating their duties in other jurisdictions.

1. The National Retail Pharmacies Have a Duty to Prevent Diversion

357. Each participant in the supply chain of opioid distribution, including the National Retail Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring and reporting suspicious activity.

358. The National Retail Pharmacies, like manufacturers and other distributors, are registrants under the CSA. 21 C.F.R. § 1301.11. Under the CSA,

pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." See 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

359. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

360. Suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

361. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions that should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and

stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

362. Suspicious pharmacy orders are red flags for, if not direct evidence of, diversion.

363. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Retail Pharmacies themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

364. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

365. Despite their legal obligations as registrants under the CSA, the National Retail Pharmacies allowed widespread diversion to occur – and they did so knowingly.

366. Performance metrics and prescription quotas adopted by the National Retail Pharmacies for their retail stores contributed to their failure. Under CVS's

Metrics System, for example, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. The result is both deeply troubling and entirely predictable; opioids flowed out of National Retail Pharmacies and into communities throughout the Cities and Counties. The policies remained in place, even as the epidemic raged.

367. Upon information and belief, this problem was compounded by the Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

368. Upon information and belief, the National Retail Pharmacies also failed to adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of

opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

369. Upon information and belief, the National Retail Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

370. Upon information and belief, the National Retail Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

371. Upon information and belief, the National Retail Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

372. The National Retail Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to

investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

2. Multiple Enforcement Actions Against the National Retail Pharmacies Confirms their Compliance Failures.

373. The National Retail Pharmacies have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the National Retail Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the National Retail Pharmacies.

a. CVS

374. CVS is one of the largest companies in the world, with annual revenue of more than $150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations. CVS could be a force for good in connection with the opioid crisis, but like other Defendants, CVS sought profits over people.

375. CVS is a repeat offender and recidivist: the company has paid fines totaling over $40 million as the result of a series of investigations by the DEA and the United States Department of Justice ("DOJ"). It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing

opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.

376. As recently as July 2017, CVS entered into a $5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.[355]

377. This fine was preceded by numerous others throughout the country.

378. In February 2016, CVS paid $8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.[356]

379. In October 2016, CVS paid $600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.[357]

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[355] Press Release, U.S. Attorney's Office E. Dist. of Cal., *CVS Pharmacy Inc. Pays $5M to Settle Alleged Violations of the Controlled Substance Act*, U.S. Dep't of Just. (July 11, 2017), https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violations- controlled-substance-act.

[356] Press Release, U.S. Attorney's Office Dist. of Md., *United States Reaches $8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances*, U.S. Dep't of Just. (Feb. 12, 2016), https://www.justice.gov/usao-md/pr/united-states-reaches-8-million-settlement-agreement-cvs-unlawful-distribution-controlled.

[357] Press Release, U.S. Attorney's Office Dist. of Conn., *CVS Pharmacy Pays $600,000 to Settle Controlled Substances Act Allegations*, U.S. Dep't of Just. (Oct. 20, 2016), https://www.justice.gov/usao-ct/pr/cvs-pharmacy-pays-600000-settle-controlled-substances-act- allegations.

380. In June 2016, CVS agreed to pay the DOJ $3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances – mostly addictive painkillers – more than 500 times between 2011 – 2014.

381. In August 2015, CVS entered into a $450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.[358]

382. In May 2015, CVS agreed to pay a $22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a

[358] Dialynn Dwyer, *CVS will pay $795,000, strengthen policies around dispensing opioids in agreement with state*, Boston.com (Sept. 1, 2016), https://www.boston.com/news/local- news/2016/09/01/cvs-will-pay-795000-strengthen-policies-around-dispensing-opioids-in- agreement-with-state.

responsibility to dispense only those prescriptions that were issued based on legitimate medical need."[359]

383. In September 2014, CVS agreed to pay $1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired. [360]

384. In August 2013, CVS was fined $350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma Cities metropolitan area.[361]

385. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.[362]

386. Despite their extensive understanding of the risks and harms of prescription opioid diversion set for above, Pharmacy Defendant CVS continues to fail to fulfill their obligations to prevent prescription opioid diversion.

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[359] Press Release, U.S. Attorney's Office M. Dist. of Fla., United States Reaches $22 Million Settlement Agreement With CVS For Unlawful Distribution of Controlled Substances, U.S. Dep't of Just. (May 13, 2015), https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful distribution.

[360] Patrick Danner, H-E-B, CVS Fined Over Prescriptions, San Antonio Express-News (Sept. 5, 2014), http://www.expressnews.com/business/local/article/H-E-BCVS- fined-over-prescriptions-5736554.php.

[361] Andrew Knittle, *Oklahoma pharmacy board stays busy, hands out massive fines at times*, NewsOK (May 3, 2015), http://newsok.com/article/5415840.

[362] Press Release, U.S. Attorney's Office W. Dist. of Okla., CVS to Pay $11 Million To Settle Civil Penalty Claims Involving Violations of Controlled Substances Act, U.S. Dep't of Just. (Apr. 3, 2013), https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penalty- claims-involving-violations-controlled.

387. Pharmacy Defendant CVS has engaged in a consistent, nationwide pattern and practice of illegally distributing prescription opioids. That pattern and practice have also affected Montana, the Cities, the Counties, and its citizens.

388. On information and belief, Pharmacy Defendant CVS regularly filled opioid prescriptions in circumstances where red flags were present.

389. On information and belief, Pharmacy Defendant CVS regularly filled opioid prescriptions that would have been deemed questionable or suspicious by a reasonably prudent pharmacy.

390. On information and belief, Pharmacy Defendant CVS has not adequately trained or supervised their employees at the point of sale to investigate or report suspicious or invalid opioid prescriptions, or protect against corruption or theft by employees and others.

391. On information and belief, Pharmacy Defendant CVS utilized monetary compensation programs for certain employees that are based, in part, on the number of prescriptions filled and dispensed. This type of compensation creates economic disincentives within the companies to change their practices. For example, these have been reports of chain store supervisory personnel directing pharmacists to fill prescriptions regardless of red flags present.

392. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for non-medical purposes.

393. Pharmacy Defendant CVS repeatedly and purposefully breached its duties under state and federal law. Such breaches are a direct and proximate cause of the widespread diversion of prescription opioids for non-medical purposes in the Cities and Counties.

394. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the Cities and Counties. This diversion and the epidemic are direct causes of harms for which Plaintiffs seek to recover.

395. The opioid epidemic in Montana, including the Cities and Counties, remains an immediate hazard to public health and safety.

396. The opioid epidemic in Montana, including the Cities and Counties, is a continuous public nuisance and remained unabated.

397. Pharmacy Defendant CVS intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

398. The Pharmacy Defendant CVS, Distributing Defendants, and Manufacturing Defendants acted pursuant to an agreement explicit or implied, in conspiracy and/or in concert of action with each other to illicitly promote and distribute opioids.

V. FIRST CAUSE OF ACTION: PUBLIC NUISANCE AGAINST ALL DEFENDANTS

399. Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

400. Manufacturing Defendants knowingly encouraged doctors in and around the Cities and Counties to prescribe, and residents to use, highly addictive opioids for chronic pain even though Manufacturing Defendants knew using opioids had a high risk of addiction and reduced quality of life. Distributor and Pharmacy Defendants knew or should have known that many of those prescription orders were not for a valid medical purpose. Nevertheless, Distributor and Pharmacy Defendants continued to disburse and distribute opioids even though upon information and belief, the evidence would suggest suspicion for diversionary purposes.

401. By doing so, Defendants purposefully interfered with Plaintiffs' public health, public safety, public peace, public comfort, and public convenience.

402. Defendants, individually and in concert with each other, have contributed to and/or assisted in creating and maintaining a condition that is harmful to the health and safety of Plaintiffs' residents, and/or unreasonably interferes with the peace and comfortable enjoyment of life in violation of Montana law.

403. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community – and the harm inflicted outweighs any offsetting benefit.

404. The staggering rates of opioid use resulting from Manufacturing Defendants' marketing efforts, combined with the high number of opioids distributed by Distributor and Pharmacy Defendants, have caused, and continues to cause, harm to the community including, but not limited to:

a) Upwards of 30% of all adults use opioids. These high rates of use have led to unnecessary opioid addiction, overdose, injuries, and deaths;

b) Children have been exposed to opioids prescribed to family members or others resulting in injury, addiction, and death. Easy access to prescription opioids has made opioids a recreational drug of choice among teenagers in the Cities and Counties; opioid use among teenagers is only outpaced by marijuana use. Even infants have been born addicted to opioids due to prenatal exposure causing severe withdrawal symptoms and lasting developmental impacts;

c) Residents of the Cities and Counties, who have never taken opioids, have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids and the loss of companionship, wages, or other support from family members who have used, become addicted to, overdosed on, or been killed by opioids;

d) More broadly, opioid use and addiction have driven the Cities and Counties residents' health care costs higher[363];

[363] *See, e.g.*, Manchikanti, Ex. A, at 14 (stating that the escalating use of opioids in high doses over long periods of time, lifetime use of long-acting drugs, or the combination has serious consequences for the costs of health care and economic stability).

e) Employers have lost the value of productive and healthy employees who have suffered from adverse consequences from opioid use;

f) Defendants' success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a new wave of addiction and injury. Defendants' scheme created both ends of a new secondary market for opioids – providing both the supply of narcotics to sell and the demand of addicts to buy them;

g) This demand has created additional illicit markets in other opiates, particularly heroin. The low cost of heroin has led some of those who initially become addicted to prescription opioids to migrate to cheaper heroin, fueling a new heroin epidemic in the process;

h) Diverting opioids into secondary, criminal markets and increasing the number of individuals who are addicted to opioids has increased the demands on emergency services and law enforcement in the Cities and Counties;

i) All of Defendants' actions have caused significant harm to the community – in lives lost; addictions endured; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and broken families and homes;

j) These harms have taxed the human, medical, public health, law enforcement, and financial resources of the Cities and Counties; and

k) Defendants' interference with the comfortable enjoyment of life of a substantial number of people is entirely unreasonable because there is limited social utility to opioid use and any potential value is outweighed by the gravity of harm inflicted by Defendants' actions.

405. Manufacturing Defendants knew, or should have known, that promoting opioid use would create a public nuisance in the following ways:

a) Defendants have engaged in massive production, promotion, and distribution of opioids for use by the citizens of the Cities and Counties;

b) Defendants' actions created and expanded the market for opioids, promoting its wide use for pain management;

c) Defendants misrepresented the benefits of opioids for chronic pain and fraudulently concealed, misrepresented, and omitted the serious adverse effects of opioids, including the addictive nature of the drugs; and

d) Defendants knew, or should have known, that their promotion would lead to addiction and other adverse consequences that the larger community would suffer as a result.

406. Manufacturing Defendants' actions were, at the least, a substantial factor in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain thereby causing opioids to become widely available and used in the Cities and Counties.

407. Without Defendants' actions, opioid use would not have become so widespread and the enormous public health hazard of opioid addiction would not have existed and could have been averted.

408. The health and safety of the citizens of the Cities and Counties, including those who use, have used, or will use opioids, as well as those affected by opioid users, is a matter of great public interest and legitimate concern to Plaintiffs'

citizens and residents. It was foreseeable to all Defendants that the burden of the opioid crisis would fall to cities and counties like the City of Great Falls, Anaconda-Deer Lodge County, Lake County, and City of Missoula in the form of social and economic costs. Specifically it was foreseeable that the Cities and Counties would sustain damages as an employer obligated to provide healthcare coverage to its employees and as a local government obligated to provide public services to its citizens.

409. The public nuisance created, perpetuated, and maintained by Defendants can be abated and further reoccurrence of such harm and inconvenience can be prevented.

410. Defendants' conduct has affected and continues to affect a considerable number of people within the Cities and Counties, and is likely to continue to cause significant harm to patients who take opioids, their families, and the community at large.

411. Each Defendant created or assisted in creating the opioid epidemic, and each Defendant is jointly and severally liable for its abatement. Furthermore, each Defendant should be enjoined from continuing to create, perpetuate, or maintain said public nuisance in the Cities and Counties. Furthermore, Defendants should compensate Plaintiffs for the funds it has expended and continues to expend for medical insurance claims for opioids that were not medically valid, as well as

increased costs of social services, health systems, law enforcement, judicial system, and treatment facilities.

VI. SECOND CAUSE OF ACTION: COMMON LAW FRAUD AGAINST ALL DEFENDANTS

412. Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

413. At all relevant and material times, Defendants expressly and/or impliedly warranted that opioids were safe, of merchantable quality, and fit for use.

414. Manufacturing Defendants' superior knowledge and expertise, its relationship of trust and confidence with doctors and the public, its specific knowledge regarding the risks and dangers of opioids, and its intentional dissemination of promotional and marketing information about opioids for the purpose of maximizing sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about the risks and harms associated with opioids.

415. At all relevant and material times, Manufacturing Defendants, individually and acting through their employees and agents, and in concert with each other, fraudulently represented to physicians, who Defendants knew would justifiably rely on Manufacturing Defendants' representations, that opioids were safe and effective for treating chronic pain.

416. Manufacturing Defendants' false representations were fraudulently made, with the intent or purpose that healthcare providers and patients would justifiably rely upon them, leading to the prescription, administration, filling, purchasing, and consumption of opioids in the Cities and Counties.

417. Distributor and Pharmacy Defendants knowingly and deliberately took advantage of the Manufacturing Defendants' false and fraudulent representations to disburse and distribute an immense amount of opioids in the Cities and Counties.

418. Distributor and Pharmacy Defendants made representations that they were taking action to prevent the opioid oversupply and abuse while recognizing they were in a unique position to do so. The Cities and Counties relied on Distributor and Pharmacy Defendants to act as a gatekeeper in the supply chain as they represented to the public.

419. Defendants' deliberate misrepresentations and/or concealment, suppression, and omission of material facts as alleged herein include, but are not limited to:

a) Making false and misleading claims regarding the known risks of the addictive nature of opioids and suppressing, failing to disclose, and mischaracterizing the addictive nature of opioids and in concomitant costs, such as overdoses, deaths, and heroin addiction;

b) Making false and misleading written and oral statements that opioids are more effective than traditional pain killers for chronic pain, or effective at all and/or omitting material

information showing that opioids are no more effective than other non-addictive drugs for chronic pain;

c) Issuing false and misleading warnings and/or failing to issue adequate warnings concerning the risks and dangers of using opioids;

d) Making false and misleading claims downplaying the risk of addiction when using opioids and/or setting forth guidelines that would purportedly identify addictive behavior;

e) Making false and misleading misrepresentations concerning the safety, efficacy and benefits of opioids without full and adequate disclosure of the underlying facts which rendered such statements false and misleading; and

f) Disbursing and distributing opioids when suspicion existed that opioids were being diverted.

420. Defendants willfully, wantonly, and recklessly disregarded their duty to provide truthful representations regarding the safety and risk of opioids, including the fact that upon information and belief, there was suspicion for diversionary purposes.

421. Defendants made these misrepresentations with the intent that the healthcare community and patients would rely to their detriment.

422. Defendants' misrepresentations were made with the intent of defrauding and deceiving the medical community and consumers to induce and encourage the sale of opioids.

423. Defendants' fraudulent representations evidence their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers living in the Cities and Counties.

424. Defendants omitted, misrepresented, suppressed and concealed material facts concerning the dangers and risk of injuries associated with the use of opioids, as well as the fact that the product was unreasonably dangerous.

425. Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of opioids.

426. Defendants' failure to stem, rather than fuel spikes of opioid sales was intended to encourage the sale of opioids, even if the circumstances provided suspicion for diversionary purposes.

427. The treating medical community and consumers in the Cities and Counties did not know that Defendants' representations were false and/or misleading and justifiably relied on them.

428. Defendants had sole access to material facts concerning the dangers and unreasonable risks of opioids, which they intentionally concealed.

429. As a direct and proximate result of Defendants' fraudulent misrepresentations and intentional concealment of facts, upon which the medical

community and consumers in the Cities and Counties reasonably relied, Plaintiffs have suffered actual and punitive damages.

VII. THIRD CAUSE OF ACTION: NEGLIGENCE AGAINST ALL DEFENDANTS

430. Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

431. Manufacturing Defendants have a duty to exercise reasonable care in marketing its opioids to physicians treating residents and the residents of the Cities and Counties. Manufacturing Defendants have breached their duty by knowingly and fraudulently misrepresenting the benefits of, and downplaying the risks of, opioids for chronic pain.

432. Manufacturing Defendants have used deceitful marketing ploys, KOLs, Front Groups, and other schemes to increase profits at the cost of public health causing an opioid epidemic. Defendants have acted willfully, wantonly, and maliciously.

433. Likewise, Distributor and Pharmacy Defendants have a duty to exercise ordinary care in distributing opioids. Distributor and Pharmacy Defendants have breached their duty by failing to prevent or reduce the distribution of opioids even if there existed suspicion for diversionary purposes. Distributor and Pharmacy Defendants have intentionally failed to prevent or reduce the distribution of opioids

so that they could increase profits. Distributor and Pharmacy Defendants have acted willfully, wantonly, and maliciously.

434. As a proximate result, Defendants and its agents have caused the Cities and Counties to incur excessive costs to treat the opioid epidemic in its the Cities and Counties, including but not limited to, increased costs of social services, health systems, law enforcement, judicial system, and treatment facilities. It was foreseeable to all Defendants that the burden of the opioid crisis would fall to cities and counties like the City of Great Falls, Anaconda-Deer Lodge County, Lake County, and City of Missoula in the form of social and economic costs. Specifically it was foreseeable that the Cities and Counties would sustain damages as an employer obligated to provide healthcare coverage to its employees and as a local government obligated to provide public services to its citizens.

435. Plaintiffs and its residents are therefore entitled to actual and punitive damages.

VIII. FOURTH CAUSE OF ACTION: GROSS NEGLIGENCE AGAINST ALL DEFENDANTS

436. Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

437. Defendants' marketing scheme to optimize profits by misrepresenting and falsely promoting opioids as the panacea to chronic pain was done intentionally.

438. Defendants' hiring of KOLs, Front Groups, and others to spread its fraudulent message that opioids were useful and beneficial for chronic pain was grossly negligent and done with conscious indifference or reckless disregard for the safety of others.

439. Distributor Defendants' distribution of opioids despite the obvious signs that there was no valid medical purpose for a large number of prescription for opioids was grossly negligent and done with conscious indifference or reckless disregard for the safety of others.

440. Each Defendant's actions and omissions as described herein, singularly or in combination with each other, were malicious resulting in damages and injuries to Plaintiffs and its residents.

441. At every stage, Defendants knew, or should have known, that their conduct would create an unreasonable risk of physical harm to others, including Plaintiffs and its residents, and should be held liable in punitive and exemplary damages to Plaintiffs.

IX. FIFTH CAUSE OF ACTION: MONTANA FOOD, DRUG, AND COSMETIC ACT AGAINST ALL DEFENDANTS

442. Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

443. Defendants have knowingly manufactured, marketed, advertised, distributed, branded, delivered, and administered opioids that have been sold, and continue to be sold, in Montana in violation of the Montana Food, Drug, and Cosmetic Act Section 50-31-105, *et seq*.

444. As alleged herein, Defendants, at all times relevant to this Complaint, violated the Montana Food, Drug, and Cosmetic Act by disseminating false advertisements about using opioids to treat chronic pain. Each Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

445. Defendants' false and misleading representations and concealments were reasonably calculated to deceive practitioners in the Cities and Counties into prescribing opioids event though they are ineffective for treating chronic pain and the risks far outweigh any benefit. Indeed, Defendants continue to make false and misleading representations to this day.

446. As a direct and proximate result of Defendants' false and misleading advertisement, Plaintiffs should be awarded civil penalties and Defendants' conduct should be enjoined pursuant to the Montana Food, Drug, and Cosmetic Act.

X. SIXTH CAUSE OF ACTION: VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT ("RICO"), 18 U.S.C. § 1961, *ET SEQ.* OPIOID MARKETING ENTERPRISE AGAINST DEFENDANTS PURDUE, CEPHALON, JANSSEN, AND ENDO (THE "RICO" MARKETING DEFENDANTS)

447. Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

448. The RICO Marketing Defendants − through the use of "Front Groups" that appeared to be independent of the RICO Marketing Defendants; through the dissemination of publications that supported the RICO Marketing Defendants' scheme; through continuing medical education ("CME") programs controlled and/or funded by the RICO Marketing Defendants; by the hiring and deployment of so-called "key opinion leaders," ("KOLs") who were paid by the RICO Marketing Defendants to promote their message; and through the "detailing" activities of the RICO Marketing Defendants' sales forces − conducted an association-in-fact enterprise, and/or participated in the conduct of an enterprise through a pattern of illegal activities (the predicate racketeering acts of mail and wire fraud) to carry-out the common purpose of the Opioid Marketing Enterprise, *i.e.*, to unlawfully increase profits and revenues from the continued prescription and use of opioids for long-term chronic pain. Through the racketeering activities, the Opioid Marketing Enterprise sought to further the common purpose of the enterprise

through a fraudulent scheme to change prescriber habits and public perception about the safety and efficacy of opioid use based on false premises. In so doing, each of the RICO Marketing Defendants knowingly conducted and participated in the conduct of the Opioid Marketing Activities by engaging in mail and wire fraud in violation of 18 U.S.C. §§ 1962(c) and (d).

449. The Opioid Marketing Enterprise alleged above, is an association-in-fact enterprise that consists of the RICO Marketing Defendants (Purdue, Cephalon, Janssen, and Endo); the Front Groups (APF, AAPM, APS, FSMB, USPF, and AGS); and the KOLs (Dr. Portenoy, Dr. Webster, Dr. Fine, and Dr. Fishman).

450. Each of the RICO Marketing Defendants and the other members of the Opioid Marketing Enterprise conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a distinct role in furthering the enterprise's common purpose of increasing profits and sales by knowingly and intentionally disseminating false and misleading information about the safety and efficacy of long-term opioid use and the risks and symptoms of addiction.

451. Specifically, the RICO Marketing Defendants each worked together to coordinate the enterprise's goals and conceal their role, and the enterprise's existence, from the public by, among other things, (i) funding, editing and distributing publications that supported and advanced their false messages; (ii) funding KOLs to further promote their false messages; (iii) funding, editing and

distributing CME programs to advance their false messages; and (iv) tasking their own employees to direct deceptive marketing materials and pitches directly at physicians and, in particular, at physicians lacking the expertise of pain care specialists.

452. Each of the Front Groups helped disguise the RICO Marketing Defendants' role by purporting to be unbiased, independent patient-advocacy and professional organizations. Instead, the Front Groups disseminated patient education materials, a body of biased and unsupported scientific "literature," and "treatment guidelines" that promoted the RICO Marketing Defendants' false messages.

453. Each of the KOLs were physicians chosen and paid by each of the RICO Marketing Defendants to influence their peers' medical practice by promoting the Marketing Defendant's false message through, among other things, writing favorable journal articles and delivering supportive CMEs as if they were independent medical professionals, thereby further obscuring the RICO Marketing Defendants' role in the enterprise and the enterprise's existence.

454. Further, each of the RICO Marketing Defendants, KOLs and Front Groups that made-up the Opioid Marketing Enterprise had systematic links to and personal relationships with each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The systematic links and personal relationships that were formed and

developed allowed members of the Opioid Marketing Enterprise the opportunity to form the common purpose and agree to conduct and participate in the conduct of the Opioid Marketing Enterprise. Specifically, each of the RICO Marketing Defendants coordinated their efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry friendly and would work together with the RICO Marketing Defendants to advance the common purpose of the Opioid Marketing Enterprise; each of the individuals and entities who formed the Opioid Marketing Enterprise acted to enable the common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

455. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each RICO Marketing Defendant and its members; (b) was separate and distinct from the pattern of racketeering in which the RICO Marketing Defendants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the RICO Marketing Defendants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including between the RICO Marketing Defendants and each of the Front Groups and KOLs; and (e) had sufficient longevity for the enterprise to pursue its purpose and functioned as a continuing unit.

456. The persons and entities engaged in the Opioid Marketing Enterprise are systematically linked through contractual relationships, financial ties, personal relationships, and continuing coordination of activities, as spearheaded by the RICO Marketing Defendants.

457. The RICO Marketing Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids, and expand the market for opioids.

458. The RICO Marketing Defendants each committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Marketing Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Marketing Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Marketing Enterprise, the U.S. Mail and interstate wire facilities. The RICO Marketing Defendants participated in

the scheme to defraud by using mail, telephones and the Internet to transmit mailings and wires in interstate or foreign commerce.

459. The RICO Marketing Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a) Mail Fraud: The RICO Marketing Defendants violated 18 U.S.C. §1341 by sending or receiving, or by causing to be sent and/or received, fraudulent materials via U.S. mail or commercial interstate carriers for the purpose of selling drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them.

b) Wire Fraud: The RICO Marketing Defendants violated 18 U.S.C. §1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, fraudulent materials by wire for the purpose of selling drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them.

460. Indeed, as summarized herein, the RICO Marketing Defendants used the mail and wires to send or receive thousands of communications, publications, representations, statements, electronic transmissions and payments to carry-out the Opioid Marketing Enterprise's fraudulent scheme.

461. Because the RICO Marketing Defendants disguised their participation in the enterprise, and worked to keep even the enterprise's existence secret, many of the precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records

maintained by the RICO Marketing Defendants, Front Groups, and KOLs. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise alleged herein depended upon secrecy. However, Plaintiffs have described the occasions on which the RICO Marketing Defendants, Front Groups, and KOLs disseminated misrepresentations and false statements to Montana consumers, prescribers, regulators and Plaintiffs, and how those acts were in furtherance of the scheme.

462. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Montana consumers, prescribers, regulators and the Cities and Counties. The RICO Marketing Defendants, Front Groups and KOLs calculated and intentionally crafted the scheme and common purpose of the Opioid Marketing Enterprise to ensure their own profits remained high. In designing and implementing the scheme, the RICO Marketing Defendants understood and intended that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the RICO Marketing Defendants' products.

463. The RICO Marketing Defendants' pattern of racketeering activity alleged herein and the Opioid Marketing Enterprise are separate and distinct from

each other. Likewise, the RICO Marketing Defendants are distinct from the Opioid Marketing Enterprise.

464. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

465. The racketeering activities conducted by the RICO Marketing Defendants, Front Groups and KOLs amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Montana consumers, prescribers, regulators and Plaintiffs. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Montana consumers, prescribers, regulators and Plaintiffs. The RICO Marketing Defendants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Opioid Marketing Enterprise.

466. Each of the RICO Marketing Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

467. As described herein, the RICO Marketing Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts

constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

468. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

469. The RICO Marketing Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs' injuries. The RICO Marketing Defendants' pattern of racketeering activity logically, substantially and foreseeably caused an opioid epidemic. Plaintiffs' injuries were not unexpected, unforeseen or independent. Rather, the RICO Marketing Defendants knew that opioids were unsuited to treatment of long-term chronic, non- acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the RICO Marketing Defendants engaged in a scheme of deception that utilized the mail and wires in order to carry-out the Opioid Marketing Enterprises' fraudulent scheme, thereby increasing sales of their opioid products.

470. It was foreseeable and expected that the RICO Marketing Defendants creating and then participating in the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme would lead to a nationwide opioid epidemic, including increased opioid addiction and overdose.[364]

471. Specifically, the RICO Marketing Defendants' creating and then participating in the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme has injured the Cities and Counties in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic. Plaintiffs' injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a) Losses caused by the decrease in funding available for Plaintiffs' public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

b) Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

c) Costs of training emergency and/or first responders in the proper treatment of drug overdoses;

d) Costs associated with providing police officers, firefighters, and emergency and/or first responders with naloxone − an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

[364] *Id.*

e) Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

f) Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

g) Costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy;

h) Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;

i) Costs associated with increased burden on Plaintiffs' judicial systems, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;

j) Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;

k) Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiffs' communities;

l) Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and

m) Losses caused by diminished property values in the form of decreased business investment and tax revenue.

472. Plaintiffs' injuries were directly and proximately caused by these Defendants' racketeering activities because they were the logical, substantial and

foreseeable cause of Plaintiffs' injuries. But for the opioid-addiction epidemic, the Cities and Counties would not have lost money or property.

473. The Cities and Counties are the most directly harmed entities and there are no other Plaintiffs better suited to seek a remedy for the economic harms at issue here.

474. Plaintiffs seek all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest.

XI. SEVENTH CAUSE OF ACTION: VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT ("RICO"), 18 U.S.C. § 1961, *ET SEQ.* OPIOID SUPPLY CHAIN ENTERPRISE AGAINST DEFENDANTS PURDUE, CEPHALON, JANSSEN, ENDO, ACTAVIS, MCKESSON, CARDINAL, AND AMERISOURCEBERGEN (THE "RICO" SUPPLY CHAIN DEFENDANTS)

475. Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

476. At all relevant times, the RICO Supply Chain Defendants were and are "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

477. The RICO Supply Chain Defendants together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States. The Opioid Supply Chain Enterprise is an association-in-fact enterprise within the meaning of § 1961. The Opioid Supply Chain Enterprise consists of the RICO Supply Chain Defendants.

478. The RICO Supply Chain Defendants were members of the Healthcare Distribution Alliance (the "HDA").[365] Each of the RICO Supply Chain Defendants is a member, participant, and/or sponsor of the HDA, and has been since at least 2006, and utilized the HDA to form the interpersonal relationships of the Opioid Supply Chain Enterprise and to assist them in engaging in the pattern of racketeering activity that gives rise to the Count.

479. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each of the RICO Supply Chain Defendants; (b) was separate and distinct from the pattern of racketeering in which the RICO Supply Chain Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Supply Chain Defendants; (d) was characterized by interpersonal relationships among the RICO Supply Chain Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose;

[365] *History*, Health Distribution Alliance, https://www.healthcaredistribution.org/about/hda-history

and (f) functioned as a continuing unit. Each member of the Opioid Supply Chain Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and resulting sales.

480. The RICO Supply Chain Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Supply Chain Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

481. The RICO Supply Chain Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Supply Chain Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Supply Chain Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Supply Chain Enterprise. The RICO Supply Chain Defendants participated in the scheme to defraud by using mail,

telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

482. The RICO Supply Chain Defendants also conducted and participated in the conduct of the affairs of the Opioid Supply Chain Enterprise through a pattern of racketeering activity by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

483. The RICO Supply Chain Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

484. Each of the RICO Supply Chain Defendants is a registrant as defined in the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of

controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

485. The RICO Supply Chain Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a) Mail Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. §1341 by sending or receiving, or by causing to be sent and/or received, fraudulent materials via U.S. mail or commercial interstate carriers for the purpose of selling drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them.

b) Wire Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. §1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, fraudulent materials by wire for the purpose of selling drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them.

486. Controlled Substance Violations: The RICO Supply Chain Defendants, who are Distributor Defendants, violated 21 U.S.C. § 823 by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA.

487. The RICO Supply Chain Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

488. The RICO Supply Chain Defendants aided and abetted others in violating the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

489. The RICO Supply Chain Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the suspicious orders that the RICO Supply Chain Defendants were filling on a daily basis – leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit market.

490. The RICO Supply Chain Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

491. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding manufacturing prescription opioids and refusing to report suspicious orders.

492. The RICO Supply Chain Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants,

victims, and methods of commission. The predicate acts were related and not isolated events.

493. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs' businesses and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the RICO Supply Chain Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

494. The pattern of racketeering activity alleged herein and the Opioid Supply Chain Enterprise are separate and distinct from each other. Likewise, the RICO Supply Chain Defendants are distinct from the enterprise.

495. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

496. Many of the precise dates of the RICO Supply Chain Defendants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy.

497. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

498. It was foreseeable to the RICO Supply Chain Defendants that Plaintiffs would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the CSA and Code of Federal Regulations allowed the widespread diversion of prescription opioids out of appropriate medical channels and into the illicit drug market—causing the opioid epidemic that the CSA intended to prevent.

499. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

500. The RICO Supply Chain Defendants' violations of law and their pattern of racketeering activity directly and proximately caused injury to Plaintiffs' businesses and property. The RICO Supply Chain Defendants' pattern of racketeering activity, including their refusal to identify, report and halt suspicious orders of controlled substances, logically, substantially and foreseeably cause an opioid epidemic. The Cities and Counties were injured by the RICO Supply Chain Defendants' pattern of racketeering activity and the opioid epidemic that they created.

501. The RICO Supply Chain Defendants knew that the opioids they manufactured and supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse.[366] Nevertheless, the RICO Supply Chain Defendants engaged in a scheme of deception, that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products by refusing to identify, report suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse, and were actually being diverted into the illegal market.[367]

502. The RICO Supply Chain Defendants' predicate acts and pattern of racketeering activity were a cause of the opioid epidemic which has injured the Cities and Counties in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic.

503. Specifically, Plaintiffs' injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a) Losses caused by the decrease in funding available for Plaintiffs' public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

b) Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other

[366] *Travelers Prop. Cas. Co. of Am.* v. *Actavis, Inc.*, 16 Cal. App. 5th 1026, 1030 (2017).
[367] *City of Everett v. Purdue Pharma L.P.*, Case No. 17-cv-00209, 2017 WL 4236062, *2 (W.D. Wash. Sept. 25, 2017).

treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

c) Costs of training emergency and/or first responders in the proper treatment of drug overdoses;

d) Costs associated with providing police officers, firefighters, and emergency and/or first responders with naloxone—an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

e) Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

f) Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

g) Costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy;

h) Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;

i) Costs associated with increased burden on Plaintiffs' judicial systems, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;

j) Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;

k) Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiffs' communities;

l) Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and

m) Losses caused by diminished property values in the form of decreased business investment and tax revenue.

504. Plaintiffs' injuries were proximately caused by Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of the Plaintiffs' injuries. But for the opioid-addiction epidemic created by Defendants' conduct, the Cities and Counties would not have lost money or property.

505. Plaintiffs' injuries were directly caused by the RICO Supply Chain Defendants' pattern of racketeering activities.

506. The Cities and Counties are the most directly harmed and there are no other Plaintiffs better suited to seek a remedy for the economic harms at issue here.

507. Plaintiffs seek all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expense of suit; and pre- and post-judgement interest, including, *inter alia*:

a) Actual damages and treble damages, including pre-suit and post-judgment interest;

b) An order enjoining any further violations of RICO;

c) An order enjoining any further violations of any statutes alleged to have been violated in this Complaint;

d) An order enjoining the commission of any tortious conduct, as alleged in this Complaint;

e) An order enjoining any future marketing or misrepresentations regarding the health benefits or risks of prescription opioids use, except as specifically approved by the FDA;

f) An order enjoining any future marketing of opioids through non-branded marketing including through the Front Groups, KOLs, websites, or in any other manner alleged in this Complaint that deviates from the manner or method in which such marketing has been approved by the FDA;

g) An order enjoining any future marketing to vulnerable populations, including but not limited to, persons over the age of fifty-five, anyone under the age of twenty-one, and veterans;

h) An order compelling Defendants to make corrective advertising statements that shall be made in the form, manner and duration as determined by the Court, but not less than, print advertisements in national and regional newspapers and medical journals, televised broadcast on major television networks, and displayed on their websites, concerning: (1) the risk of addiction among patients taking opioids for pain; (2) the ability to manage the risk of addiction; (3) pseudoaddiction is really addiction, not a sign of undertreated addiction; (4) withdrawal from opioids is not easily managed; (5) increasing opioid dosing presents significant risks, including addiction and overdose; (6) long term use of opioids has no demonstrated improvement of function; (8) use of time-released opioids does not prevent addiction; (9) abuse-deterrent formulations do not prevent opioid abuse; and (10) that manufacturers and distributors have duties under the CSA to monitor, identify, investigate, report and halt suspicious orders and diversion but failed to do so;

i) An order enjoining any future lobbying or legislative efforts regarding the manufacturer, marketing, distribution, diversion, prescription, or us of opioids;

j) An order requiring all Defendants to publicly disclose all documents, communications, records, data, information, research or studies concerning the health risks or benefits of opioid use;

k) An order prohibiting all Defendants from entering into any new payment or sponsorship agreement with, or related to, any: Front Group, trade association, doctor, speaker, CME, or any other person, entity, or association, regarding the manufacturer, marketing, distribution, diversion, prescription, or use of opioids;

l) An order establishing a National Foundation for education, research, publication, scholarship, and dissemination of information regarding the health risks of opioid use and abuse to be financed by the Defendants in an amount to be determined by the Court;

m) An order enjoining any diversion of opioids or any failure to monitor, identify, investigate, report and halt suspicious orders or diversion of opioids;

n) An order requiring all Defendants to publicly disclose all documents, communications, records, information, or data, regarding any prescriber, facility, pharmacy, clinic, hospital, manufacturer, distributor, person, entity or association regarding suspicious orders for or the diversion of opioids;

o) An order divesting each Defendant of any interest in, and the proceeds of any interest in, the Marketing and Supply Chain Enterprises, including any interest in property associated with the Marketing and Supply Chain Enterprises;

p) Dissolution and/or reorganization of any trade industry organization, Front Group, or any other entity or association associated with the Marketing and Supply Chain Enterprises identified in this Complaint, as the Court sees fit;

q) Dissolution and/or reorganization of any Defendant named in this Complaint as the Court sees fit;

r) Suspension and/or revocation of the license, registration, permit, or prior approval granted to any Defendant, entity, association or enterprise named in the Complaint regarding the manufacture or distribution of opioids;

s) Forfeiture as deemed appropriate by the Court; and

t) Attorney's fees and all costs and expenses of suit.

XII. EIGHTH CAUSE OF ACTION: UNJUST ENRICHMENT AGAINST ALL DEFENDANTS

508. Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

509. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by the Cities, the Counties, and its residents.

510. When Plaintiffs and its residents purchased opioids, they expected that Defendants had provided necessary and accurate information regarding those risks. Instead, Defendants had misrepresented the material facts regarding the risks and benefits of opioids and distributed or disbursed opioids even though, upon information and belief, there was suspicion for diversionary purposes.

511. Defendants took undue advantage and received a benefit because the Cities and Counties bore the cost of the externalities of Defendants' wrongful conduct. Moreover, the Cities and Counties had no choice and was effectively required to cover these costs to Defendants' benefit.

512. Defendants have been unjustly enriched at the expense of Plaintiffs, and Plaintiffs are therefore entitled to damages to be determined by the jury.

XIII. NINTH CAUSE OF ACTION: CIVIL CONSPIRACY AGAINST ALL DEFENDANTS

513. Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

514. Defendants engaged in a civil conspiracy in their unlawful marketing of opioids and/or distribution of opioids into Montana and Plaintiffs' communities.

515. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful marketing of opioids and/or distribution of opioids into Montana and Plaintiffs' communities.

516. Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids.

517. The Marketing Defendants further unlawfully marketed opioids in Montana and Plaintiffs' communities in furtherance of that conspiracy.

518. Defendants' conspiracy and acts in furtherance thereof are alleged in detail in this Complaint, including, without limitation, in Plaintiffs' Counts for violations of RICO. Such allegations are specifically incorporated herein.

519. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly caused the injuries alleged herein.

520. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

521. Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue engaging in their unlawful conduct.

522. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

523. Defendants' actions demonstrated both malice and also aggravated and egregious fraud. Defendants engaged in the Conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct has a

great probability of causing substantial harm. Marketing Defendants' fraudulent wrongdoing was also particularly gross.

524. Defendants' misconduct alleged in this case is ongoing and persistent.

525. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

526. Plaintiffs have incurred expenditures for special programs over and above Plaintiffs' ordinary public services.

527. Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray:

a) That the acts alleged herein be adjudged and decreed to be unlawful and that the Court enter a judgment declaring them to be so;

b) That Defendants be enjoined from, directly or indirectly through KOLs, Front Groups or other third parties, continuing to misrepresent the risks and benefits of the use of opioids for chronic pain, and from continuing to violate Montana law;

c) That Plaintiffs recover all measures of damages, including punitive and exemplary damages, allowable under the law, and that judgment be entered against Defendants in favor of Plaintiffs;

d) That Plaintiffs recover restitution on behalf of Plaintiffs' consumers who paid for opioids for chronic pain;

e) That Plaintiffs recover the costs and expenses of suit, pre- and post-judgment interest, and reasonable attorneys' fees as provided by law; and

f) That Defendants be ordered to abate the public nuisance that they created in in violation of Montana common law; and

g) That the Court grant any other relief that it deems warranted.

Date: February 6, 2019

Respectfully Submitted,

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